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**THE POSITIVE AFFECT REGULATION IN AN ONLINE
TRANSDIAGNOSTIC PROTOCOL FOR EMOTIONAL DISORDERS**

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TRANSDIAGNOSTIC PROTOCOL FOR EMOTIONAL DISORDERS**

Memoria presentada por Amanda Díaz García para optar al grado de
doctor/a por la Universitat Jaume I

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Presentation

This doctoral dissertation takes the form of a compendium of publications, including articles indexed in renowned journals and international scientific publications. At the time of writing, 3 articles were published and 3 other papers had been submitted to scientifically relevant journals for review and subsequent acceptance. The present doctoral dissertation is made up of 8 chapters that include each of the articles mentioned. As all the chapters are written as separate articles for publication in scientific journals, they have their own entity and can be read independently. The co-authors of all the papers have expressed their agreement that the doctoral candidate present the work as a doctoral dissertation, as well as their express renunciation of presenting it as part of another doctoral dissertation. In accordance with the regulations governing doctoral studies regulated by Royal Decree 99/2011 (which modifies Royal Decree 1393/2007 of 29 October, to which this doctoral dissertation is inscribed) at the Universitat Jaume I, for the modalities of Doctorate with an international mention and Doctorate by compendium of publications, the scientific articles that make up this doctoral dissertation and general introduction and discussion have been written in English, the usual language for scientific communication.

Chapter 1: General introduction

General introduction

This chapter encompasses a general preface to the thesis. This dissertation is framed within the psychological interventions intended to treat Emotional Disorders (ED) from a transdiagnostic perspective. Furthermore, it provides an overview of the importance of positive affect (PA), exploring the effect of adding, in an online transdiagnostic treatment protocol, a specific therapeutic component to up-regulate PA. Finally, the use of technology and the Internet is emphasized, in terms of dissemination and increasing access to these interventions.

The chapter begins with a short overview of Emotional Disorders (ED) and the role of emotion regulation underlying many clinical disorders. Next, evidence-based psychological treatments developed for the treatment of ED are described. After that, the transdiagnostic perspective is presented, as well as the role of neuroticism/extraversion (negative and positive affect) as the essential processes underlying ED. Finally, the use of Internet-based treatments is highlighted.

At the end of this general introduction, a section for research questions and an outline of the thesis will be presented, pointing out the general objective of the present thesis as well as the specific objectives and the hypotheses.

Emotional Disorders: the role of emotion regulation

In recent years, there has been an increase in the attention paid to the emotional disorders (ED), defined as anxiety and unipolar mood disorders, due to their impact on mental health. The National Comorbidity Survey Replication (NCS-R; conducted from 2001 to 2003) for the evaluation of mental disorder prevalence found that the lifetime prevalence of anxiety disorders was 28.8%, and 20.8% for mood disorders, with major depressive disorder being the most prevalent lifetime disorder (16%) (Kessler, Berglund, Demler, Jin, Merikangas, Walters, et al., 2005). These disorders disrupt the lives of millions of people each year, and they are one of the main causes of disability worldwide (McLean, Asnaani, Litz, & Hofmann, 2011; Kazdin & Rabbitt, 2013). ED are considered particularly detrimental in the domains of home, social, and close-relationship functioning, in comparison with common chronic medical disorders (Druss et al., 2009), and it is even projected that, by 2030, depression will be the main cause of disability worldwide, ahead of ischemic heart disease, traffic accidents, chronic pulmonary disease, and HIV/AIDS (WHO, 2008).

An important concept in understanding ED is emotion regulation, defined by Gross a few years ago as strategies used by an individual to manipulate an emotion's occurrence, experience, duration, intensity, and expression (Gross, 1998). Literature has shown the role of emotion regulation deficits in a range of clinical disorders such as substance abuse (Hayes, Wilson, Gifford, Follette, & Strosahl, 1996), generalized anxiety disorder (Mennin, Heimberg, Turk, & Fresco, 2002), and complex posttraumatic stress disorder (Cloitre & Rosenberg, 2006). However, the development of Linehan's theoretical work on the role of emotion regulation in borderline personality disorder (BPD) (Linehan, 1993) has been considered the most comprehensive work highlighting the function of emotion dysregulation. Linehan states that emotion dysregulation is one of the central features of BPD and underlies many of the associated disturbances of this disorder.

In the field of ED, research has shown that people with ED tend to use maladaptive ways of responding to emotions (i.e. emotion dysregulation), including lack of awareness and understanding of emotions, difficulties controlling behaviors in the face of emotional distress, and deficits in the modulation of emotional arousal (Gratz & Roemer, 2004). In addition, scientific literature has pointed out that people with ED have difficulties in the different emotion regulation processes identified by Gross (1998): situation selection, situation modification, attentional deployment, cognitive change, and response modulation (Gross, 2015).

A relevant aspect of the study of emotional regulation is its transdiagnostic value because many disorders share difficulties in emotion regulation. This finding provides very relevant data for better understanding mental disorders from a transdiagnostic perspective and achieving changes in the development of new psychological interventions (Barlow, Allen, & Choate, 2004; Sloan et al., 2017; Stanton, Rozek, Stasik-O'Brien, Ellickson-Larew, & Watson, 2016).

Despite awareness that the prevalence of EDs is high and growing, and that they disrupt the lives of millions of people each year (McLean et al., 2011), less than 50% of people suffering from ED receive adequate treatment (Bebbington et al., 2000). As Wang et al., 2009 reported, approximately 60% of individuals with a mental disorder do not receive treatment, and only 33% of the treated patients are classified as receiving at least minimally adequate treatment. Thus, there is a compelling need to implement innovative and even radical

solutions to ensure that the aid reaches everyone in need (Emmelkamp et al., 2014 Haro et al., 2014).

Evidence-based psychological treatments (EBTs)

A broad range of evidence-based psychological treatments (EBTs) has been developed to directly address the large worldwide treatment needs (Kazdin, 2015). Indeed, numerous EBTs have been shown to be effective in the treatment of ED (Nathan & Gorman, 2016). Rigorous review processes, such as the National Institute for Health and Care Excellence (NICE), have concluded that EBTs are frontline sole or adjunctive interventions for a wide range of mental disorders (Clark, 2011; Layard & Clark, 2014). However, there is very poor access to EBTs and great difficulty in disseminating these interventions, which might be due in large part to their costs, the duration of the treatments, or the lack of well-qualified professionals (Ellard, Fairholme, Boisseau, Farchione, & Barlow, 2010). A number of different barriers to using EBTs have been pointed out, related to various levels of analysis: patient-level (i.e. problems such as transport, childcare, low motivation, or lack of awareness of EBTs), therapist-level (i.e. therapist beliefs of adverse impact on the therapeutic relationship), treatment-level (i.e. difficulty identifying the appropriate EBT), organization-level (i.e. skepticism that a new treatment will help), and government-level (i.e. lack of providers trained in EBTs) (Harvey & Gumpert, 2016). In addition, the development of EBTs has been accompanied by diagnosis-specific treatment manuals (with separate handbooks, workbooks, and protocols to tackle one presenting disorder at a time), which may result in a substantial decline in the dissemination of EBTs (McHugh & Barlow, 2010). Whereas disorder-specific treatment protocols focus on a categorical approach, there is a growing body of research emphasizing a more parsimonious and dimensional approach based on the considerable overlap among different ED (Barlow, 2004).

Transdiagnostic perspective

The co-occurrence of anxiety and mood disorders has been reported, with rates ranging between 40 and 80% (Kessler, Berglund, Demler, Jin, Merikangas, Walters, et al., 2005). Particularly, the comorbidity between anxiety disorder and major depressive disorder (MDD) is one of the most prevalent comorbid psychiatric conditions (McGlinchey & Zimmerman, 2007; Naragon-Gainey, 2010). These high rates of comorbidity have been associated with the chronicity and severity of psychopathology, treatment outcome and relapse, treatment seeking,

suicide potential (e.g. Brown, Antony, & Barlow, 1995), and increased distress, disability, and service utilization (Andrews, Slade, & Issakidis, 2002).

With the objective of simultaneously treating more than one disorder (e.g. anxiety and depression, or multiple anxiety disorders) and improving treatment efficiency, transdiagnostic CBT programs have been developed in the past few decades (Barlow, Allen, & Choate, 2004; Erickson, 2003; Farchione et al., 2012; Titov, Andrews, Johnston, Robinson, & Spence, 2010). Transdiagnostic approaches emphasize the core common features underlying different disorders. In the field of ED, it has been emphasized that these disorders share common biological and psychological vulnerabilities, as Barlow proposed in the model referred to as “triple vulnerabilities” (Barlow, 2002; Brown & Barlow, 2009). These three different but related types of vulnerability are: generalized biological vulnerability (heritable and involving nonspecific genetic contributions), generalized psychological vulnerability (associated with changes in brain function due to adverse early life experiences), and specific psychological vulnerability (emerging from early learning and explaining why one emotional disturbance develops instead of another) (Barlow, 2002). Evidence suggests that the two generalized vulnerabilities are involved in the development and expression of the ED (Brown & Barlow, 2009; Brown, 2007).

As previously mentioned, transdiagnostic approaches have important implications for the treatment of ED. Clark (2009) distinguished three transdiagnostic perspectives. The first is the transdiagnostic practice, whose goal is to include components of various intervention protocols in a specific treatment. The second perspective is called transdiagnostic theory, which outlines the common constructs that are important in the appearance and maintenance of ED. In this vein, a well-recognized theoretical approach that can be considered transdiagnostic is the tripartite model of anxiety and depression. This model points out the general tendency to experience negative affectivity in anxiety and depression, the low positive affectivity specific to depression, and the physiological hyperarousal specific to most anxiety states, but especially to panic disorder (Clark & Watson, 1991). Finally, the third perspective on transdiagnostic treatments is Barlow’s Unified Protocol (UP) for ED, which combines the previous two perspectives and builds an intervention based on commonalities of ED (Allen, McHugh, & Barlow, 2008; Ellard et al., 2010). The UP is a transdiagnostic, emotion-focused, cognitive-behavioral treatment for ED that emphasizes the role of emotion regulation (Barlow et al., 2014) and focuses on four essential aspects

with the general purpose of down-regulating NA: addressing emotional avoidance, promoting cognitive flexibility, and facilitating exposure to avoided situations and sensations. Moreover, it places special emphasis on increasing present-focused emotional awareness. The UP has been shown to be effective (Farchione et al., 2012), with improvements maintained at 18-month follow-up (Bullis, Fortune, Farchione, & Barlow, 2014). In addition, the UP has had empirical support across different disorders, such as anxiety disorders (Barlow et al., 2017; Ellard et al., 2010; Farchione et al., 2012), depression (Boswell, Anderson, & Barlow, 2014), bipolar disorder (Ellard, Deckersbach, Sylvia, Nierenberg, & Barlow, 2012), and borderline personality disorder (Sauer-Zavala, Bentley, & Wilner, 2016).

Research describing the essential processes underlying ED has indicated that people suffering from an ED have higher levels of neuroticism/negative affect/behavioral inhibition (N/NA/BI) (Brown & Barlow, 2009). Research findings on personality have provided support for the perspective that neuroticism is a shared component of depressive and anxiety disorders, and that it is particularly elevated in people with comorbid disorders (Weinstock & Whisman, 2006). It has been suggested that negative reactivity to the emotional experience and the use of inadequate strategies for emotional regulation are fundamentally connected with neuroticism and the pathology present in ED (Barlow et al., 2014). The effect of the UP has been shown on the two temperament dimensions of N/BI and extraversion/behavioral activation (Carl, Gallagher, Sauer-Zavala, Bentley, & Barlow, 2014).

In recent years, a growing body of research has emerged showing the efficacy of transdiagnostic treatments. In the field of anxiety disorders, transdiagnostic treatments have been shown to be effective in open trials (Norton, 2008; Norton & Hope, 2005; see meta-analysis by Norton & Philipp, 2008), compared to diagnosis-specific CBT for anxiety (Norton & Barrera, 2012; Pearl & Norton, 2016), in Internet-based transdiagnostic treatments (Titov et al., 2010; Carlbring et al., 2011), and for multiple anxiety disorders in primary care (Roy-Byrne et al., 2010). Furthermore, the efficacy of these transdiagnostic treatments has also been shown for comorbid depression and anxiety disorders (Dear et al., 2011; Titov et al., 2011; Farchione et al., 2012; Norton et al., 2013). Moreover, the efficacy and effectiveness of transdiagnostic treatment protocols for ED have been shown in several meta-analyses (Newby, McKinnon, Kuyken, Gilbody, & Dalgleish, 2015; Newby, Twomey, Yuan Li, & Andrews, 2016;

Reinholt & Krogh, 2014; Păsărelu, Andersson, Bergman Nordgren, & Dobrea, 2017). Some of these meta-analyses also conclude that transdiagnostic protocols obtain similar results to EBTs for specific disorders (Mcevoy, Nathan, & Norton, 2009; Olatunji, Cisler, & Deacon, 2010; Richards & Richardson, 2012).

The data suggest that transdiagnostic treatments might be more widely effective across diverse mental health problems, addressing different disorders with a single protocol (Clark & Taylor, 2009). In this regard, participants with comorbid anxiety or depression are able to learn different strategies to target core symptoms relevant to multiple diagnoses, without having to participate in several disorder-specific protocols.

Nevertheless, transdiagnostic protocols have focused on reducing NA, and less attention has been paid to promoting PA or modifying risk factors. It is, therefore, necessary to develop and test treatment components that focus on enhancing protective factors and resilience. Literature has highlighted the potential importance of positive emotionality as a treatment component (Bolier et al., 2013; Roepke & Seligman, 2016; Pressman, Jenkins, & Moskowitz, 2019).

Positive affect

Despite the importance of positive emotions, the study of positive affect has been missing or very scarce in clinical settings, and existing research on emotion regulation in ED has primarily focused on the regulation of negative emotions rather than positive emotions (Carl, Soskin, Kerns, & Barlow, 2013). However, positive affect regulation has important implications for both the conceptualization and treatment of ED. Evidence suggests that people with emotional disturbances have deficits in positive emotional functioning. Thus, low levels of positive affect are associated with unipolar depression (Watson & Naragon-Gainey, 2010), whereas excesses in positive affect are associated with risk of bipolar disorders (Gruber, Johnson, Oveis, & Keltner, 2008). Regarding the specific relationship between depression and positive emotion regulation processes, people with depression experience a loss of interest in pleasurable activities (APA, 2000), avoid a wide range of positive situations (Lewinsohn & Amenson, 1978), and exhibit difficulty engaging in approach-related behavior (Shankman, Klein, Tenke, & Bruder, 2007). Depressed individuals also show selective attention biases toward negative stimuli (Bar-Haim, Lamy, Pergamin, Bakermans-Kranenburg, & Van Ijzendoorn, 2007) and present automatic negative interpretive biases (this aspect is also shared with anxiety disorders)

(Mathews & MacLeod, 2005). Likewise, with regard to anxiety, people with anxiety disorders also avoid positive activities due to apprehension related to experiencing positive emotions (Turk, Heimberg, Luterek, Mennin, & Fresco, 2005), have automatic selective attention biases toward negative stimuli, maintained even in conditions where the stimuli are masked, and tend to make negative appraisals of ambiguous scenarios (Mathews & MacLeod, 2005). Finally, as in depression, individuals with anxiety disorders report increased downregulation and decreased maintenance/upregulation of positive emotions. In sum, the disturbances in ED can be broadly characterized as excessive avoidance and downregulation of positive emotions (Carl et al., 2013).

Positive emotions are considered core elements of mental health, optimizing health, functioning, and well-being (Dockray & Steptoe, 2010; Lyubomirsky, King, & Diener, 2005). Several benefits have been associated with positive affectivity, such as generating protective factors or reducing the risk of developing mental symptoms and disorders (Keyes, Dhingra, & Simoes, 2010; Wood & Joseph, 2009). In addition, positive emotions are associated with beneficial cognitive, physiological, and behavioral changes (Fredrickson, 2001). Research has also indicated that increased positive emotions are associated with greater achievement of personal goals in the long term (Lyubomirsky et al., 2005). Moreover, the “broaden-and-build theory”, proposed by Fredrickson, (2001) highlights the difference between the role of negative and positive emotions. Negative emotions warn of danger and help one to survive, whereas positive emotions strengthen the thought-action repertoires, extend perceptual and cognitive abilities, and help to build new repertoires and physical, intellectual and social resources (Fredrickson & Branigan, 2005). In addition to reducing the frequency and duration of NA, attention should also be paid to increasing the frequency and duration of PA (Fredrickson & Losada, 2005). All this evidence suggests that it is crucial to define the role of PA and consider how to strengthen them because there has also been a significant tendency to dampen or “cool” them in depressed people (Werner-Seidler, Banks, Dunn, & Moulds, 2013).

Despite the accumulating data about the potential benefits of the use of procedures to promote positive emotions (i.e. resilience, optimism), and the importance of disturbances in positive affectivity in ED, these deficits have not received sufficient attention as treatment targets (Quoidbach & Gross, 2015), and few interventions with positive psychological components to up-regulate PA have been developed.

Incorporating positive emotions into treatment (i.e. emotion-focused treatments) might help maintain long-term gains and buffer against relapse by strengthening an individual's enduring coping resources and resiliency (Ehrenreich, Fairholme, Buzzella, Ellard, & Barlow, 2007).

Internet-based treatments

To date, the dominant delivery format in psychotherapy has been individual face-to-face contact; however, it is much more expensive and time-consuming than other formats, such as guided self-help and Internet-based treatments (Vos, Huibers, Diels, & Arntz, 2012). With the objective of overcoming some of these limitations of face-to-face interventions, a new development has emerged with the introduction of e-health (Barak, 2008; Griffiths & Christensen, 2007), in which the outcome of individual therapy might be enhanced by the implementation of new forms of technology-assisted clinical tools (e.g. self-help, virtual reality, or minimal contact therapies). E-health is defined here as “the use of information and communication technologies to improve psychological care” (Lal & Adair, 2014). Treatments for mental health problems provided via the Internet are also called web-based interventions, which are defined as “treatments, typically behaviourally based, that are operationalized and transformed for delivery via the Internet. Usually, they are highly structured; self-guided or partly self-guided; based on effective face-to-face interventions; personalized to the user; interactive; enhanced by graphics, animations, audio, and video; and tailored to provide follow-up and feedback” (Ritterband, Andersson, Christensen, Carlbring, & Cuijpers, 2006). These interventions can be used for the assessment and treatment of clinical conditions, and they have been shown to be an effective and efficient way of providing treatment for a wide range of psychological disorders (Andersson, 2016; Peñate & Fumero, 2016), including depression and anxiety disorders (Andersson & Cuijpers, 2009). Moreover, data from meta-analyses reveal that these interventions are as efficacious as face-to-face traditional treatments (Andrews, Cuijpers, Craske, McEvoy, & Titov, 2010; Cuijpers et al., 2011; Cuijpers, van Straten, Warmerdam, & Andersson, 2009).

Authors propose that self-administered treatments over the Internet have a series of advantages at different levels, such as: a) greater accessibility, they are accessible at any time and place, reducing travel time and costs for both clinicians and participants; b) versatility, participants can work at their own pace and go through materials as often as they like; c) anonymity, participants can

avoid stigmatization; d) scalability, which refers to the ability of interventions shown to be effective in a research setting to be expanded under real world conditions. Finally, other advantages have been reported with regard to the potential for integrating the techniques learned in the person's daily life routine, due to a emphasis on participants' active role and the safety, acceptance, cost-effectiveness, and convenience of these interventions (Andersson & Titov, 2014; Andrews, Newby, & Williams, 2014; Penate, 2012). In addition, Internet-based treatments can facilitate the availability of EBTs (Kazdin & Blase, 2011; Botella et al., 2009; Kazdin, 2015).

Research questions

In recent years, there has been an increase in the attention to the ED, defined as anxiety and unipolar mood disorders, due to their impact on mental health. ED are among the most prevalent mental disorders (anxiety disorders, 28.8%; mood disorders, 20.8%), with comorbidity rates ranging between 40 and 80%. A broad range of evidence-based psychological treatments (EBTs) have been shown to be effective in the treatment of ED. However, less than 50% of people suffering from ED receive the appropriate treatment. This situation has led to the development of new intervention proposals based on the transdiagnostic perspective, which tries to address the underlying processes common to ED. The data suggest that transdiagnostic treatments are effective across diverse mental health problems, addressing different disorders with a single protocol. Nevertheless, transdiagnostic protocols have focused on NA, and less attention has been paid to promoting PA or modifying risk factors. Evidence suggests that people with ED have deficits in positive emotional functioning, and so new interventions focusing on these problems are greatly needed. In addition, there is a compelling need to implement innovative and even radical solutions to ensure that the aid reaches everyone in need, and Information and Communication Technologies can be very useful. Internet-based treatments (IBTs) can facilitate the availability of EBTs.

From the information mentioned above, we can conclude that the treatment of ED is feasible. However, despite the effectiveness of psychological interventions and new developments in mental health care, several open questions in ED interventions remain unanswered.

- (1) The inclusion of components to up-regulate PA in psychological interventions has received little empirical attention in clinical settings, which makes it important to study the feasibility of these interventions in order to determine whether they should be recommended for efficacy testing
- (2) In line with the importance of the use of procedures to promote resilience (such as positive emotions and optimism), some meta-analyses have examined the effects of resilience interventions in the treatment of different disorders. However, in recent years, more studies have been conducted in the field of positive emotionality, with the incorporation of numerous IBTs. Hence, it is possible to estimate the overall effect size

with more precision and analyze the methodological and theoretical adequacy of these interventions.

- (3) Although several transdiagnostic interventions have been developed for the treatment of ED, no controlled studies (RCT) have been published investigating the efficacy of a transdiagnostic Internet-based treatment with a specific component to address PA in a community sample of patients with ED.
- (4) IBTs have been found to be efficacious and effective for a wide range of disorders, including ED. However, many aspects, such as dropout rates, still have to be studied in order to conclusively show their effectiveness. Very few studies have qualitatively explored the experiences of patients who drop out of IBTs.
- (5) Positive affect has been considered a core element of mental health and suggested as a necessary treatment component for ED. However, without an adequate and reliable measure of PA, it is not feasible to conduct research that provides empirical support in this field. The Positive and Negative Affect Schedule (PANAS) is the most widely and frequently used scale to assess PA and NA. This scale has been validated on clinical samples such as forensic samples, psychiatric outpatients, substance users, and adult women with fibromyalgia. Nevertheless, the psychometric properties of this scale have not yet been examined in Spanish clinical samples with anxiety, depressive, and adjustment disorders. In addition, the proliferation of IBTs has led to the development of a wide range of assessments conducted online, using digital versions of pen and paper self-report questionnaires, which may differ in psychometrics properties. In this vein, the need for validated assessments applied online is increasingly evident.

This leads to the following **research questions** addressed in this doctoral dissertation:

- Which is the feasibility of including a component focused on up-regulating PA into a psychological treatment for people suffering from depressive symptoms?
- What is the effectiveness of Internet-based training interventions in improving PA and resilience?
- Is a transdiagnostic Internet-based intervention with a specific component to address PA effective:

- to treat ED in terms of depressive and anxious symptomatology?
 - to improve PA (up-regulate PA)?
- What are the potential barriers that can prevent acceptance of these transdiagnostic Internet-based treatments and may influence the dropout rates?
- Is the PANAS a reliable enough measurement of PA in a Spanish clinical sample of patients with anxiety, depressive, and adjustment disorders to be included as a primary outcome of PA in the RCT?

Objectives

The general objective of the present dissertation was to analyze, in a randomized controlled study, the efficacy of a transdiagnostic Internet-based treatment for ED in a community sample, including a specific component to up-regulate positive affect or not, versus a waiting list control group. In relation to the above-mentioned approaches and findings, the research group LabPsiTec (Universitat Jaume I) developed a manualized protocol for ED based on the classic perspectives derived from the UP (Barlow et al., 2004) and some strategies from Marsha Linehan's protocol (Linehan, 1993). This protocol was first tested in terms of feasibility in a series of cases, showing that the intervention was feasible, not only for reducing depression, anxiety, and NA, but also for increasing PA and the orientation towards enjoyment (Mira et al., 2018). This study suggested that the promotion of positive feelings, cognitions, and behaviors through positive psychology strategies might have an impact on decreasing clinical symptomatology (Vazquez, Hervas, & Ho, 2006).

Once the feasibility of the protocol had been tested, a more specific objective was to adapt the protocol to a multimedia web platform (video, images, etc.) in order to apply it over the Internet. However, prior to this development, a systematic review and meta-analysis was carried out in the field of online psychological interventions designed to promote resilience. This study allowed us to synthesize the available evidence about the effectiveness of Internet-based training interventions for improving resilience, positive emotions, and quality of life. Based on the results of the meta-analysis, we designed and developed an Internet-based treatment for ED based on the transdiagnostic perspective, adapting the manualized protocol to the web. The protocol included core components mainly addressed to down-regulating NA (i.e. present-focused emotional awareness and acceptance, cognitive flexibility, behavioral and emotional avoidance patterns, and interoceptive and situational exposure) as well as a PA-regulation component in order to promote psychological strengths and enhance well-being (Sin & Lyubomirsky, 2009) (i.e. behavioral activation strategies (Lejuez, Hopko, & Hopko, 2001), strategies to promote pleasant and significant activities linked to values and life goals, and strategies to enhance personal strengths, positive feelings, positive cognitions, and positive behavior (Seligman & Csikszentmihalyi, 2000). This component also included strategies from Well-being Therapy (WBT) (Fava, 1999; Fava & Ruini, 2003) and some notions of Fredrickson's Broaden-and-Build Theory to explain the mechanisms

behind positive emotions (Fredrickson, 2001). Traditional therapeutic components of evidence-based treatments for ED (i.e. Psychoeducation, Motivation for change, and Relapse prevention) were also incorporated.

After designing the treatment protocol and adapting it to the web, we conducted the Randomized Controlled Trial (RCT), included in this thesis as one of the main objectives, to test the efficacy of this transdiagnostic Internet-based treatment for ED with a specific therapeutic component to directly up-regulate positive affect applied online.

This study aims to contribute to the literature on the efficacy of transdiagnostic approaches to emotional disorders in general, and it more specifically seeks to explore the possible impact of a specific component designed to up-regulate positive affect. Combining a transdiagnostic approach with an online therapy format, and adding the specific component for positive affect, may help to achieve a clear impact on the design and application of future transdiagnostic treatment protocols for ED, as a way to more effectively address the temperament vulnerabilities, that is, the core aspects of these disorders. Furthermore, this intervention could contribute to improving the efficiency and effectiveness of current treatment programs for ED, promoting the dissemination of EBTs, and helping to decrease the high prevalence of ED.

Another objective of this dissertation was the study of dropout rates from a transdiagnostic online intervention from a qualitative perspective. In this regard, the experiences of patients who drop out of the transdiagnostic Internet-based treatment mentioned above were analyzed. This study allowed us to better grasp the phenomenon of dropout from IBTs and delineate specific implications in terms of research, training, and practice.

Finally, due to the importance of considering adequate and reliable measures of PA and the inclusion of the Positive and Negative Affect Schedule (PANAS) (one of the most widely and frequently used scales to assess PA and NA) as one of the primary outcomes in our RCT, the psychometric properties of the scale were examined in Spanish clinical samples with anxiety, depressive, and adjustment disorders.

Outline of the thesis

The present doctoral thesis consists of a compendium of publications covering five main specific chapters, each of them written as a separate article for publication in scientific journals (see Table 1-1). **Chapter 1** provides a general introduction to the dissertation. **Chapter 2** presents feasibility data from a positive clinical psychology intervention for depressive symptoms. **Chapter 3** reports on the results of a meta-analysis examining the effectiveness and theoretical adequacy of online interventions aimed to promote resilience and positive affect (PA). **Chapter 4** describes the study protocol of the randomized controlled trial that evaluates a transdiagnostic Internet-based treatment for emotional disorders with a specific component to address PA. **Chapter 5** presents the findings regarding the clinical effectiveness of the transdiagnostic Internet-based treatment for both depressive and anxious symptomatology, and for PA. **Chapter 6** describes the findings of the qualitative analysis of the experiences of clients who dropped out of the transdiagnostic IBT. **Chapter 7** presents the psychometric properties of the PANAS in Spanish clinical samples with anxiety, depressive, and adjustment disorders. Finally, in **Chapter 8**, the dissertation concludes with a general discussion that includes a critical examination of clinical implications and directions for future research.

Table 1-1. Doctoral dissertation as a compendium of publications

Chapter	Article
2	Mira A., Enrique A., Díaz-García A. , Rachyla I., González-Robles A., Bretón-López J., and Botella C. (2018). Feasibility of a positive clinical psychology intervention for depressive symptoms: A series of cases.
3	Díaz-García, A. , Franke, M., Herrero, R., Ebert, D., Botella, C. Theoretical adequacy, methodological quality and efficacy of online interventions targeting resilience: a systematic review and meta-analysis.
4	Díaz-García, A. , González-Robles, A., Fernández-Álvarez, J., García-Palacios, A., Baños, R. M., & Botella, C. (2017). Efficacy of a Transdiagnostic internet-based treatment for emotional disorders with a specific component to address positive affect: Study protocol for a randomized controlled trial. <i>BMC psychiatry</i> , 17(1), 145.
5	Díaz-García, A. , González-Robles, A., Fernández-Álvarez, J., Bretón-López, J. García-Palacios, A., Baños, R. M., & Botella, C. Positive affect regulation in an online transdiagnostic protocol for emotional disorders: a randomized controlled trial.
6	Fernández-Álvarez, J., Díaz-García, A. , González-Robles, A., Baños, R., García-Palacios, A., & Botella, C. (2017). Dropping out of a transdiagnostic online intervention: A qualitative analysis of client's experiences. <i>Internet Interventions</i> , 10, 29-38.
7	Díaz-García, A. , González-Robles, A., Mor, S., Mira, A., Quero, S., García-Palacios, A., Baños, R. M., & Botella, C. Positive and Negative affect Schedule (PANAS): psychometric properties for the online version in a Spanish clinical sample with emotional disorders.

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Chapter 2: Feasibility of a positive clinical psychology intervention for depressive symptoms: A series of cases

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Feasibility of a positive clinical psychology intervention for depressive symptoms: A series of cases

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Abstract

Introduction: Traditionally, evidence-based treatments for depression have focused on clinical symptoms. The combination of positive psychological strategies and traditional approaches has received little empirical attention in clinical settings.

Objective: The development and implementation of a positive clinical psychology protocol for depressive symptoms.

Method: The protocol was applied in five depressed patients. Depression, anxiety, affect and orientation towards enjoyment were measured at pre-, post-treatment, and at 3-month follow-up. Opinion on the program was also assessed.

Results: The intervention was feasible, not only for reducing depression, anxiety and negative affect, but also for increasing positive affect and orientation towards enjoyment.

Conclusions: It is important to continue to investigate the development of interventions focusing on both negative and positive aspects of human functioning.

Keywords: cognitive-behavioral therapy, depressive symptoms, positive clinical psychology, well-being.

Introduction

Depression is estimated to be the second leading cause of disability worldwide (Ferrari et al., 2013; Haro et al., 2014), and it has high personal, social and economic costs (Cuijpers, Beekman & Reynolds, 2012). Thus, the prevention and treatment of depression should be a global health priority (Cuijpers, Beekman & Reynolds, 2012; Bentley, Gallagher, Carl, & Barlow, 2014).

Currently, depression can be treated effectively with psychotherapy (especially cognitive behavioral therapy), pharmacological interventions, or a combination of the two (Cuijpers, van Straten, Andersson, & van Oppen, 2008; Cuijpers, Beekman & Reynolds, 2012). Furthermore, prevention of depression seems feasible and may be an effective way to delay or prevent the onset of depressive disorders (van Zoonen et al., 2014). However, until recently, these evidence-based interventions (cognitive behavioral therapy, behavior therapy, and interpersonal therapy) focused on the clinical symptoms and on reducing negative emotions (Nathan & Gorman, 2016). Following the WHO definition (1946) of mental health, health is more than just the absence of mental illness. It has been defined as *“a state of well-being in which the individual realizes his or her own abilities, can cope with the normal stresses of life, can work productively, and is able to make a contribution to his or her community...”* (WHO, 2014, p.1). Mental health also implies positive expectations about the future, adaptive ways of interpreting reality, and positive emotional states (Edmondson & MacLeod, 2014). Furthermore, prevention should also include the promotion and development of the individual's strengths by fomenting protective variables that empower him/her, acting as barriers and shields that would reduce vulnerability to suffering from mental disorders (WHO, 2004). Thus, it is necessary to develop psychological interventions for depression that not only focus on the deficits and discomfort, but also aim to improve individuals' strengths and the promotion of well-being (Vázquez & Hervás, 2008).

In this regard, the positive psychology (PP) framework emerges as a necessary complement to the Cognitive Behavioral Therapy (CBT) approach (Park, Peterson & Sun, 2013). Meta-analyses have shown that positive psychological interventions (PPIs) work, and that they are effective for enhancing well-being measures and reducing depressive symptoms in the general public

and in individuals with specific psychosocial problems (Bolier et al. 2013; Sin & Lyubomirsky, 2009).

In the clinical setting, the inclusion of PPIs as a treatment component has received little empirical attention. It has been suggested that PPIs could help to improve recovery rates for psychological problems such as depression, reducing their residual effects and preventing relapses (Fava et al., 2005; Vázquez & Hervás, 2006). Thus, some authors claim that it is important to achieve an integration between the disciplines of clinical psychology and PP (Johnson & Wood, 2015; Maddux, 2008; Rashid, 2009; Wood & Tarrrier, 2010). These authors have suggested the term “Positive Clinical Psychology”, and they argue that the constructs studied by positive psychologists (hope, optimism, etc.) are important because they can interact with risk factors to predict outcomes, producing greater resilience. It should be noted that PP emerged for supportive purposes, and not to replace what we know about suffering, weakness, and psychological disorders (Johnson & Wood; 2015; Seligman, Steen, Park & Peterson, 2005; Vázquez & Hervás, 2008). However, the literature includes few studies with interventions that integrate PP and traditional clinical psychology (Bolier et al, 2012; Meyer et al, 2009).

Taking into consideration the need to develop positive clinical interventions that integrate CBT and PP components, the present study is designed to present the development of an 8-week, individual, manualized, positive clinical psychology protocol for the treatment of depressive symptoms. Furthermore, we present feasibility data for this protocol in a series of cases, and discuss the potential benefits of this positive clinical psychology intervention, focusing on the specific characteristics of each patient. These findings may help to guide intervention strategies to ameliorate depression and enhance well-being in clinical settings.

Materials and Method

Participants

The description of each patient and his/her scores on the pre-treatment measures are displayed in Table 2-1 Five people (3 women and 2 men) took part in the study from those seeking help at the Emotional Disorders Clinic in Jaume I University. The mean age was 30.8 years (SD = 8.95), ranging from 23 to 46 years. One participant was single, four were married, and one was divorced. Four participants were university students or had already finished their university

studies, and one participant had basic studies. Regarding the diagnosis, three participants met DSM-IV criteria for Depression, and two were suffering from depressive symptoms.

The diagnosis was carried out by Ph.D. students trained in the application of the MINI and supervised by expert clinicians. The inclusion criteria were: age between 18–65 years old; willingness to participate in the study; and having depressive symptoms (from minimal to severe according to the BDI-II). The exclusion criteria considered were: currently receiving psychological treatment or having received another psychological treatment in the past year; having a severe Axis I mental disorder: abuse or dependence on alcohol or other substances, psychotic disorder, or dementia; and the presence of a suicidal ideation or plan (evaluated by item 9 of the BDI-II). All the patients were asked to sign an informed consent.

Table 2-1. Individual case summaries

Case (age) gender	Diagnosis	Measures	Scores at pre- treatment	Background
P1 (25) female	Depression	BDI-II	22	P1 was a graduate student. She described persistent feelings of indifference, emptiness, and uselessness. The patient reported frequent negative thoughts about herself (e.g., "You are worthless") and the future (e.g., "You will never find a job"). In addition, because of concentration difficulties, as well as loss of interest and motivation, she was neglecting her studies. Although this situation exacerbated her emotional distress and negative thinking, she maintained her social relationships and daily activities.
		OASIS	7	
		PANAS+	17	
		PANAS-	28	
P2 (46) male	Depression	BDI-II	34	P2 was a baker. He reported low mood and continued discomfort in almost all situations. He felt very irritable, and this caused him to have confrontations with his family. He explained that he did not enjoy anything he did. He was discouraged, with little desire to get up, and with no hope about anything. In his worst moments, he came to think that life was not worthwhile. He viewed the future with hopelessness, feeling uncertain about it and worried about work.
		OASIS	9	
		PANAS+	22	
		PANAS-	27	
P3 (27) female	Depression	BDI-II	42	P3 was an undergraduate student. She described low mood, loss of motivation, lack of energy, and deep feelings of failure (e.g., "I am unable to do anything", "I feel overwhelmed", "I have not made any progress in my life") in the past few months. She also reported lack of interest in doing things, tiredness, and negative thoughts (e.g., "I am never going to get out of this hole", "everything will go wrong"). Feelings of anxiety emerged frequently, especially in unexpected situations. She reported not being able to deal with new situations and feeling even more incompetent.
		OASIS	15	
		PANAS+	15	
		PANAS-	36	

P4 (23) male	Depressive symptoms	BDI-II	22	P4 was a student. His main complaint was high emotional lability, featured with depressive symptoms and a pronounced reduction in interest in things he used to enjoy. Furthermore, he referred to somatic symptoms, such as headaches and persistent restlessness. He reported spending the day sleeping and thinking about his problems. This functioning pattern turned into a great weakness and inability to engage in his studies.
		OASIS	8	
		PANAS+	29	
		PANAS-	13	
P5 (31) female	Depressive symptoms	BDI-II	14	P5 was an undergraduate student. She reported low mood, somatic symptoms (stomach pain and nausea), low self-esteem, and problems in coping. In addition, she had suffered the loss of important relatives in her life (parents and uncle). Therefore, she had difficulties in carrying out her daily activities, and she had stopped doing things that she used to like (e.g. read or write in her blog).
		OASIS	9	
		PANAS+	17	
		PANAS-	24	

Measures

The measures used in the study are: Diagnostic Interview:

Mini-International Neuropsychiatric Interview (MINI) (Sheehan et al., 1997). It is a short, structured diagnostic psychiatric interview that yields key DSM-IV and ICD-10 diagnoses (Sheehan et al., 1997). The MINI can be administered in a short period of time, and clinical interviewers only brief training. It has been translated and validated in Spanish (Ferrando et al., 1998).

Primary outcome measures:

Beck Depression Inventory (BDI-II) (Beck, Steer, & Brown, 1990). It is one of the most widely-used questionnaires to evaluate depression severity in pharmacological and psychotherapy trials. It consists of 21 items about the different symptoms characterizing major depression disorder, added together to obtain the total score, which can yield a maximum of 63 points. The instrument has shown good internal consistency ($\alpha = 0.76$ to 0.95). The Spanish version of this instrument has also shown high internal consistency ($\alpha = 0.87$) for both general and clinical populations ($\alpha = .89$) (Sanz, Navarro, & Vázquez, 2003).

Positive and Negative Affect Scale (PANAS) (Watson, Clark, & Tellegen, 1988). The PANAS consists of 20 items that evaluate two independent dimensions: positive affect (PA) and negative affect (NA). The range for each scale (10 items on each) is from 10 to 50 (Watson et al., 1988). It is a brief, reliable, and valid self-report measure, and has shown excellent convergent and divergent validity (Watson et al., 1988). The Spanish version has demonstrated high internal consistency ($\alpha = 0.89$ and 0.91 for PA and NA in women, respectively, and $\alpha = 0.87$ and 0.89 for PA and NA in men, respectively) in college students (Sandín et al., 1999).

Secondary outcome measures:

Overall Anxiety Severity and Impairment Scale (OASIS) (Norman, Cissell, Means-Christensen, & Stein, 2006). The OASIS consists of a 5-item questionnaire, rated from 0 to 4, that assesses the frequency and severity of anxiety symptoms. The instrument also provides measures of avoidance, as well as work, academic, social, and everyday life impairment related to anxiety symptoms. A psychometric analysis of the OASIS scale found good internal consistency ($\alpha = .80$), test-retest reliability ($k = .82$) and convergent validity for this instrument. We translated the OASIS into Spanish and began its validation process. The validation data confirmed the factorial structure and reliability and

validity data obtained by the original authors (internal consistency in both populations, general and clinical ($\alpha = .0.86$ and test-retest reliability ($k = .84$) (Mira et al., 2015).

Enjoyment Orientation Scale (EOS; Hervás and Vázquez, 2006). The EOS is a new tool related to the behavioral activation system, which is believed to regulate appetitive motives. The EOS assesses the degree to which participants try to be receptive to and engage in pleasant things (anticipatory pleasure). It contains 6 items that represent different expressions of this construct (e.g. “I almost always try to enjoy new things every day, no matter how small”), rated on a Likert scale from 1 (“strongly disagree”) to 7 (“strongly agree”) (Hervás, et al., 2009).

Opinion of Treatment Scale. This questionnaire is adapted from Borkovec and Nau (Borkovec & Nau, 1972). The content of the five items, rated on a scale from 0 to 10, covers how logical the treatment seemed, to what extent it could satisfy the patient, whether it could be recommended to a person with the same problem, whether it could be used to treat other psychological problems, and its usefulness for the patient’s problem.

Clinical psychology intervention protocol

Therapists

The therapists involved in the study were Clinical Psychologists (with at least a Clinical Psychology master degree or a PhD) trained in Cognitive Behavioral Therapy (CBT). They were also trained to administer the MINI interview and monitored by a supervisor. The Clinical Psychologists applied the MINI interview to establish each participant’s clinical diagnosis under the supervision of two Senior Clinical Psychologists.

“Manualization” of the intervention

We developed two manualized protocols. First, a therapist guide was written in sufficient detail to provide appropriate instructions for therapists, including the explanation of concepts and therapeutic procedures. These guidelines were designed to help mental health professionals step by step. In addition, a workbook was prepared for patients as a way to review the content of the session and practice all the work done. This manual introduces the explanation of important concepts and techniques through vignettes and images (see Figure 2-1 as an example), in order to facilitate their understanding.

Likewise, patients were asked to carry out tasks and exercises related to the content of each module.

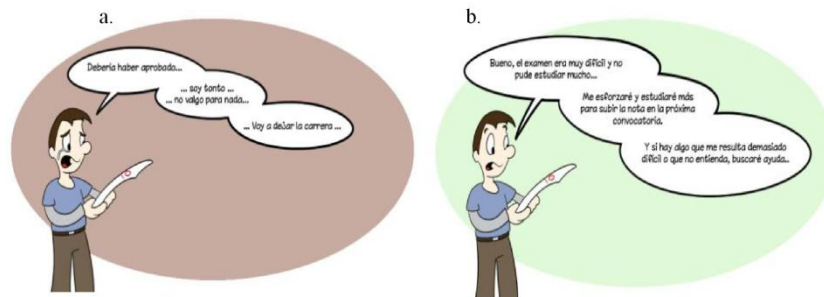


Figure 2-1. Illustrative vignettes showing maladaptive (a) and adaptive (b) ways of coping

Content translation for element (a): "I should had passed... | I'm stupid ... I'm worthless | I'm going to quit the university". Content translation for element (b): "Well, the exam was very hard and I couldn't study enough... | I'll try my best and study more to get a better mark next time. | And if I find something too difficult, I'll search for help".

Content development

The intervention includes components of evidence-based treatments for depression (Natham & Gordman, 2016). The whole protocol stresses the importance and benefits of being active and staying involved in life, values, and goals. It allows the individual to learn and practice adaptive ways to cope with depressive symptoms and confront daily problems. Specifically, some components of Barlow's Unified Protocol have been adapted, namely, motivation, psychoeducation, cognitive therapy, and relapse prevention (Barlow, Ellards et al., 2011). Furthermore, the program incorporates a Behavioral Activation component (BA) (Lejuez, Hopko & Hopko, 2001), and it also includes a component of PP, offering strategies to promote and enhance personal strengths, positive feelings, positive cognitions, and positive behavior (Seligman & Csikszentmihalyi, 2000; Sin & Lyubomirsky, 2009). These therapeutic components are implemented through 8 modules. Each module has specific objectives (outlined in

Table 2-2).

Table 2-2. Intervention protocol

Module/ Psychological component	Objectives	Homework tasks
1. Motivation for change/ Motivation	<ul style="list-style-type: none"> • To analyze the advantages and disadvantages of changing • To emphasize the importance of being motivated • To highlight the importance of establishing significant life goals 	<ul style="list-style-type: none"> ✓ Read the content of this module and review all the material included. ✓ Fill out the Decisional Balance Board and reflect on the pros and cons of change ✓ Establish significant life goals and the steps to achieve them
2. Understanding emotional problems/ Psychoeducation	<ul style="list-style-type: none"> • To provide information to recognize and understand emotional problems • To understand the problems and difficulties as a part of daily life, seeing them as an opportunity to learn and grow. 	<ul style="list-style-type: none"> ✓ Read the content of this module and review all the material included.
3. Learning to move on/ Behavioral Activation	<ul style="list-style-type: none"> • To teach the importance of 'moving on' to acquire a proper level of activity and involvement in life, and perform meaningful, satisfying activities linked to their values • To understand that abandoning activities, which occurs when there is unrest, is not beneficial, but worsens the problems. • To understand the importance of completing a diary of daily activities and the level of satisfaction with them 	<ul style="list-style-type: none"> ✓ Read the content of this module and review all the material included. ✓ Complete the diary of daily activities every day
4. Learning to be flexible/ Cognitive Flexibility	<ul style="list-style-type: none"> • To be more flexible cognitively and to be able to see life situations from different perspectives • To understand the importance of maladaptive ways of thinking in the maintenance of emotional disorders, and in learning how to identify and change them. 	<ul style="list-style-type: none"> ✓ Read the content of this module and review all the material included. ✓ Practice the identification of Erroneous Thoughts and Cognitive Flexibility ✓ Complete the diary of daily activities every day

5. Learning to enjoy/ Positive Psychology	<ul style="list-style-type: none"> ● To see the importance of positive emotions in evolution, and in broadening our intellectual, physical, and social resources. ● To teach procedures that generate positive experiences, promoting involvement in pleasant and significant activities, and having contact with others. ● To learn how to enjoy positive experiences and “savor” positive aspects of life in order to enhance wellbeing. ● To know the importance of the smile and its positive consequences. 	<ul style="list-style-type: none"> ✓ Read the content of this module and review all the material included. ✓ Divide the week between: smile Days and no-smile Days ✓ Search for a moment of enjoyment every day: concentrate and experience it fully ✓ Savor the little things every day: it becomes a habit ✓ Complete the diary of daily activities every day
6. Learning to live/ Positive Psychology	<ul style="list-style-type: none"> ● To learn the difference between positive experiences, which merely represent moments of momentary pleasure, and the achievement of psychological well-being. ● To understand the importance of identifying the individual’s own psychological strengths and carrying out meaningful activities linked to values and goals in life. ● To understand the concept of flow and the importance of performing activities in this way ● To start to live a meaningful and valuable life 	<ul style="list-style-type: none"> ✓ Read the content of this module and review all the material included. ✓ Select and record activities linked to values and significant areas of life (easy start) ✓ Focus on the present and catch the good times (record) ✓ Complete the diary of daily activities every day
7. Living and learning / Positive Psychology	<ul style="list-style-type: none"> ● To develop an action plan to boost the individual’s psychological strengths and start working for life and the future ● To understand that life is a process of continuous learning, change, and personal growth. ● To learn strategies to foster strengths and identify and capture moments of wellbeing. 	<ul style="list-style-type: none"> ✓ Read the content of this module and review all the material included. ✓ Gratitude: ✓ 3 pluses: Record once a day three things you are thankful for and why. Re-read and experience that emotion every night. ✓ Your best memory: Remember something positive and rewarding. Thank life for having it. ✓ Visit of gratitude: Thank you letter to someone else. Experience the feeling shared with the other person. ✓ Getting to express gratitude: Think of a person you want to thank (e.g. gift, kiss, hug,

		etc.
		✓ Curiosity: Search for active interest topics or activities
		✓ Hope: Encourage optimism and positive affect by writing a short story about your ideal future
		✓ Devote 5 minutes every night to visualizing it
		✓ Complete the diary of daily activities every day

8. From now on, what else...?/ Positive Psychology	<ul style="list-style-type: none"> • Learning that the end of the program is only the beginning of the path of each one, and inviting to think about how they would like their future and life, following the motto: <i>Every morning, a new day full of possibilities begins for you.</i> • Strengthening the strategies learned throughout the program, scheduling the future practice and teaching how to identify and cope with future high- risk situations. 	<ul style="list-style-type: none"> ✓ Summarizing the things learned in each module ✓ Carrying out the exercise: What goals I would like to achieve? ✓ Choosing a positive life motto, based on different heuristics, for example: <i>The richest person is the one who knows how to enjoy the best pleasures without spending a penny.</i>
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Setting and context

Individual face-to-face sessions took place at the Emotional Disorders Clinic at University. The sessions took 60 to 90 minutes per week over a period of 8 weeks. However, they could be extended to 12 weeks, depending on how quickly the participants understood and applied the specific tasks and abilities. Furthermore, all the therapists were monitored by clinical supervisors who ensured the correct application of the intervention protocol and solved any doubts the therapists might have.

Session format

The structure of the sessions followed a similar format each time. At the beginning, the therapist began by asking questions related to the previous session in order to find out whether the patient understood and integrated the content of each module or whether there were doubts to resolve. If patients had difficulties in completing any of the homework tasks, they were helped and encouraged to keep doing them. After that, the contents of the corresponding

module were explained. Finally, at the end of each session, homework tasks were assigned, and patients were given the specific module of the workbook to review. Homework tasks were strongly recommended in order to consolidate everything learned in the session. At the beginning of the next session, patients were asked if they had any doubts, questions, or anything to discuss in order to resolve them.

Design

A longitudinal design was employed to explore potential differences in the outcome measures after an 8-week intervention program, comparing these scores with the pre-assessment, and at three-month follow-up. Furthermore, the study was approved by the Ethics Committee of the Jaume I University.

Procedure

The five patients sought help for their low mood at the Emotional Disorders Clinic in Jaume I University. All the participants underwent a screening assessment; those who met all the inclusion and exclusion criteria were told about the treatment protocol and then asked to sign a consent form. Next, the participants completed the pre-treatment assessment (the measures explained in the *Measures* section, with the exception of the Opinion of treatment scale), and the treatment protocol was applied. Finally, all the participants were assessed again at post-treatment, with the same measures plus the *Opinion of Treatment Scale*, in order to assess satisfaction with the treatment.

Data analysis

Each participant's raw primary and secondary data are presented. Descriptive statistics (means and standard deviations) were obtained through the software SPSS version 22.0. To estimate the magnitude of the intervention, effect sizes (Cohen's *d*) and 95% confidence intervals were calculated for the primary and secondary outcome measures. To interpret effect sizes, we used Cohen's convention (1988), according to which an effect size of 0.20 is considered small, 0.50 is considered moderate, and 0.80 and above is considered large. To estimate the clinical significance of the changes shown at post-treatment and at the 3-month follow-up, Clinical Significance Change (CSC) was calculated using Jacobson and Truax's index (1991) for all measures. In addition, the participants were classified into one of the following groups proposed by Kupfer (1991): (1) Recovered, (2) Improved, (3) No change; or (4) Deteriorated. The "Recovered" group included participants who showed CSC on the outcome measure and had

a final score within the range of functional or the normal population. Participants were classified in the “Improved” group when, despite having achieved CSC, their final score was still within the range of dysfunctional or the clinical population. Finally, if participants did not achieve CSC, or this CSC was in the direction of greater dysfunctionality, participants were classified in the “No change” and “Deteriorated” groups, respectively.

Results

Post-treatment and follow-up changes

Table Table 2-3 describes the means, standard deviations, and within-treatment effect sizes (Cohen’s *d*) for the different measures. In the case of the pre-treatment scores, the average scores on the BDI-II matched a diagnosis of moderate depression symptoms (Sanz, García-Vera, Espinosa, Fortún & Vázquez, 2005). In the case of PANAS+, the pre-treatment scores were below the standard average, and for PANAS-, the scores were above the standard average (Crawford & Henry, 2004). With regard to OASIS, pre-treatment scores were very close to the cut-off point that indicates the presence of anxiety (from 11-20; Norman et al., 2011).

Regarding change from the pre- to post-treatment scores, all the measures of negative symptoms (BDI-II, OASIS and PANAS-) reached a large effect size. In addition, a large effect size was also found for both positive measures (PANAS + and EOS). Effect sizes were non-significant in all the analyses because of the sample size; however, they showed a trend toward improvement. Moreover, on those measures where the average scores were in the dysfunctional range (BDI-II and PANAS), scores obtained at post-treatment reached the functional range. At the 3-month follow-up, the trend toward improvement continued for nearly all the outcomes, both positive and negative, with the exception of PANAS-, where the scores stabilized.

Table 2-3. Descriptive statistics for primary and secondary measures (N=5)

Measures	Mean (SD)			Within- group effect size, <i>d</i> [95% CI]	Within- group effect size, <i>d</i> [95% CI]
	Pre- Treatment	Post- Treatment	3-month FU	Pre- Post- Treatment	Pre- F-up
BDI-II	26.80 (11.10)	11.40 (14.31)	6.33 (4.04)	1.11 [-0.34; 2.56]	1.48 [-1.03; 3.98]
PANAS +	20 (6.25)	31.40 (7.23)	32.33 (4.73)	1.46 [-3.23; 0.31]	1.58 [-3.40; 0.25]
PANAS -	29 (4.47)	17 (7.35)	18 (11.27)	2.15 [-0.35; 4.65]	1.97 [-0.82; 4.76]
OASIS	9.60 (3.13)	4.40 (4.01)	2 (3.46)	1.33 [-0.51; 3.17]	1.94 [-0.30; 4.19]
EOS	22 (4.95)	27.20 (5.07)	28.67 (3.21)	0.84 [-1.48; 0.21]	1.08 [-2.80; 0.65]

Note. BDI-II: Beck Depression Inventory; PANAS +: Positive Affect; PANAS -: Negative Affect; OASIS: Overall Anxiety Severity and Impairment; Enjoyment Orientation Scale

CSC at post-treatment and three-month follow-up

Table 2-4 presents individual participants' scores on the BDI, the OASIS, the PANAS and the EOS at the pre- intervention (Pre), post-intervention (Post) and the three-month follow-up (F/up). CSC is also indicated. Figure 2-2 represents the individual participants' scores on the primary outcome measures (BDI and PANAS).

The reliable change index analysis showed that two of the five participants presented a clinically significant decrease in their BDI scores at post-intervention. Both of these participants fell into the “Recovered” group. At follow-up, CSC was observed in four participants. Three of them were classified in the “Recovered” group and one in the “Improved” group. On OASIS and PANAS, three participants showed CSC at both assessment moments. On OASIS, the three participants were classified in the “Recovered” group and on PANAS in the “Improved” group. Finally, two participants achieved CSC on EOS at post-intervention, and four did so at follow-up. At post-intervention, one participant fell into the “Recovered” group, and the other fell into the “Improved” group. At follow-up, three participants were classified as “Recovered” and one as “Improved”.

Table 2-4. Participants' self-report questionnaire scores at pre intervention, post intervention and 3-month follow-up with clinically significant change

Measure	Assessment	Participants				
		P1	P2	P3	P4	P5
BDI ^c	Pre	22	34	42	22	14
	Post	10	0 [*]	36	3 [*]	8
	F/up	7 [*]	2 [*]	21 [*]	7 [*]	10
OASIS ^c	Pre	7	9	15	8	9
	Post	8	0 [*]	7 [*]	0 [*]	7
	F/up	5	0 [*]	6 [*]	0 [*]	6
PANAS _b +	Pre	17	22	15	29	17
	Post	33 [*]	40 [*]	28 [*]	35	21
	F/up	39 [*]	36 [*]	24	34	27 [*]
PANAS _b -	Pre	28	27	36	30	24
	Post	26	10 [*]	23 [*]	10 [*]	16
	F/up	23	11 [*]	25 [*]	12 [*]	31
EOS ^a	Pre	21	16	26	19	28
	Post	29 [*]	35 [*]	24	26	22
	F/up	36 [*]	31 [*]	34 [*]	25	30 [*]

Note. BDI-II: Beck Depression Inventory; PANAS +: Positive and Negative Affect Scale (Positive affect sub-scale); PANAS -: Positive and Negative Affect Scale (Negative affect sub-scale); OASIS: Overall Anxiety Severity and Impairment Scale; EOS: Enjoyment Orientation Scale; ^c The criterion used was C from the Jacobson and Truax index (1991). ^b The criterion used was B from the Jacobson and Truax index (1991). ^a The criterion used was A from the Jacobson and Truax index (1991); * Clinically significant change

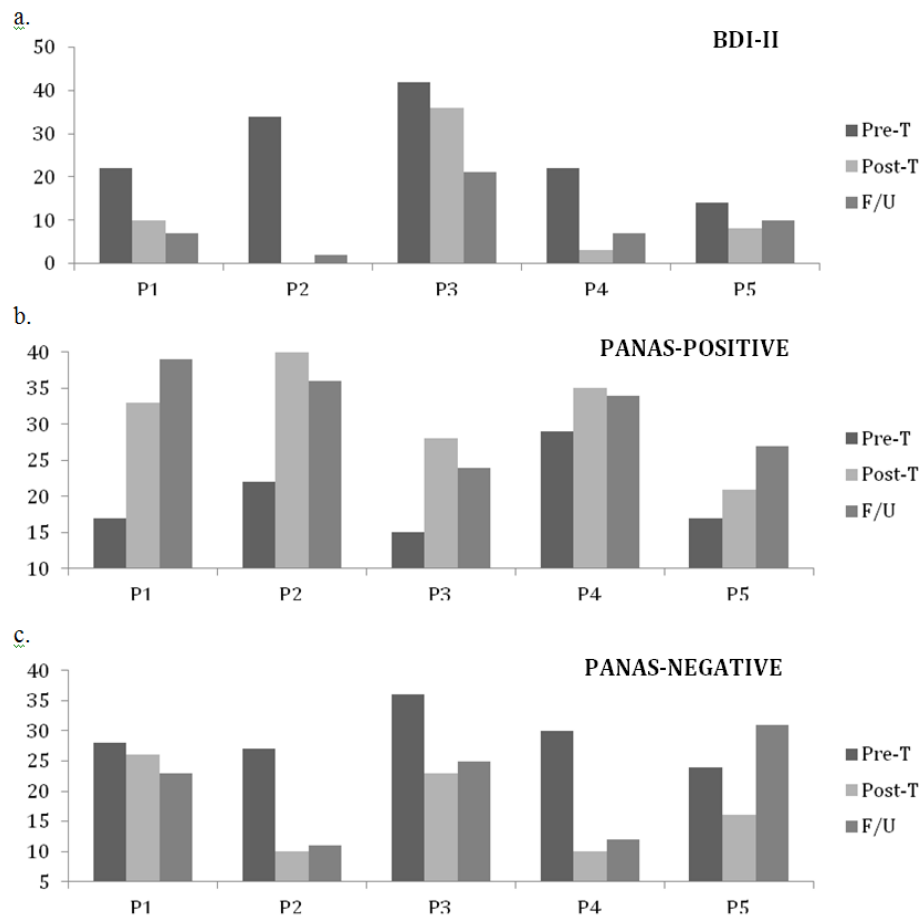


Figure 2-2. Individual scores for each patient (P1, P2, P3, P4, P5) in the (a) BDI-II, (b) Panas-Positive and (c) Panas-Negative at pre- and post-treatment, and at the 3-month follow-up Pre-T: Pre-treatment; Post-T: Post-treatment; F/up: 3-month follow-up

Opinion of the participants

All participants reported high scores (between 8.00 and 9.40): logic of the treatment, satisfaction with the treatment, recommendation of the treatment to other people with similar problems, and usefulness of the treatment, both for other psychological problems and for their own specific problem.

The results of the opinion of treatment are shown in Table 2-5.

Table 2-5. Means and standard deviations for the items on the opinion scale (N=5)

Item	Mean(SD)
1. How logical does the therapy offered to you seem?	8.80 (.83)
2. How satisfied are you with the therapy offered to you?	9.00 (1.00)
3. How confident would you be in recommending this therapy to a friend with the same problem?	9.40 (.54)
4. How useful do you think this treatment would be in improving other psychological problems?	8.00 (1.41)
5. How useful do you think this treatment has been in reducing your symptoms?	8.80 (1.30)

Discussion

The aim of the present study was to describe a positive clinical psychology protocol for depression and present data about its feasibility and acceptability levels.

The data collected suggest that the intervention was feasible, not only for reducing depression, anxiety and negative affect, but also for increasing positive affect and orientation toward enjoyment. These results are in line with the assumptions of different authors who suggest that the promotion of positive feelings, cognitions, and behaviors through PP strategies might have an impact on decreasing clinical symptomatology (Lambert & Pasha-Zaidi, 2014; Vázquez & Hervás, 2006).

Focusing on patients with a diagnosis of MDD, (P1, P2, P3), the intervention was found to be useful, and all the participants showed substantial improvements on all the variables at the end of the treatment that were maintained at follow-up. The results suggest that this protocol achieved two goals that are considered essential in the treatment of patients with low mood (Vázquez & Hervás, 2008; WHO, 2004), that is, reducing discomfort and negative emotions, along with promoting strengths and increasing positive emotions. Likewise, important improvements in enjoyment orientation were reported, suggesting that the protocol helped patients to be involved in meaningful activities to improve well-being. Engagement in activities that are pleasant and related to personal goals and values in life is, according to the literature, an

important factor to consider in the treatment of depression (Kanter, Puspitasari, Santos & Nagy, 2012).

In the case of the two patients with depressive symptoms (P4, P5), where the aim was the reduction in clinical symptomatology and prevention of depression, both participants improved their clinical symptoms on all the variables at the end of the treatment. Furthermore, they improved their scores on positive affect. Regarding the maintenance of the improvements until follow up, both patients maintained their improvements on the clinical variables (depression and anxiety), with the exception of negative affect in P5, who suffered a stressful life event during the follow-up. Despite the increase in negative emotions, the improvements in positive affect levels were maintained in both participants, and the joy orientation levels also improved at follow -up. Improvements in positive affect and enjoyment orientation could work as protective variables buffering the impact of depressive symptoms and daily problems that might arise in the future, as in the case of P5 (Fredrickson, 2001; Vera-Villaruel, Celis-Atenas, Morales, Silva, Contreras, & Lillo, 2016).

Regarding the opinion of the participants, they reported feeling very satisfied with the treatment, and they found it very logical and useful, even for other psychological problems. In addition, they would recommend it to a friend. High rates of treatment acceptability are important to enhance the effectiveness of interventions (Esther, De Graaf, Huibers, Riper, Gerhards, & Arntz, 2009). It is necessary to continue to explore the best fit between therapeutic procedures and patients' preferences in order to offer more tailored treatments based on their needs (Schueller, 2011). In this regard, PP could play a role in filling this gap because it focuses on improving positive aspects such as virtues and psychological strengths, which are also important factors to develop in patients with depressive symptoms (Vazquez & Hervas, 2008).

This study is based on a manualized positive clinical psychology protocol that combines two evidence-based complementary approaches, namely CBT and PP, and it was applied by well-trained psychologists. The implementation of standardized protocols has been found to be predictive of better psychotherapeutic outcomes (Crits-Christoph et al. 2001; Forand et al. 2011). Furthermore, interventions with specific structures and goals would make good professional training and dissemination easier (Gaston, Abbott, Rapee & Neary, 2006).

This study has limitations. First, it has a case series design with all the corresponding external validity threats. Second, due to the low number of participants, the high effect sizes found in this study are limited by the large and non-significant confidence intervals shown in most measures. Third, this study does not report the effects of the intervention beyond the 3-month follow-up. Therefore, it is unknown whether the effects are maintained in the long term. Additionally, the efficacy of this intervention in improving the general functioning of patients with depressive symptoms in both the short and long term should be evaluated in a large, controlled trial.

Conclusions

Overall, the present study supports a truly integrative psychology approach, suggested by different authors using the term positive clinical psychology (Maddux, 2008; Rashid, 2009; Wood & Tarrier, 2010). The development of interventions with a focus on both negative and positive aspects of human functioning will allow a more comprehensive psychotherapy (Rashid, 2009). Furthermore, as more studies emerge in this area, these fields will become more unified.

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Chapter 3: Theoretical adequacy, methodological quality and efficacy of online interventions targeting resilience: a systematic review and meta-analysis

This chapter has been submitted as:

Díaz-García, A., Franke, M., Herrero, R., Ebert, D., Botella, C. Theoretical adequacy, methodological quality and efficacy of online interventions targeting resilience: a systematic review and meta-analysis.

Theoretical adequacy, methodological quality and efficacy of online interventions targeting resilience: a systematic review and meta-analysis

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Abstract

Introduction: The evidence base supporting the inclusion of positive affect components in psychological treatments to promote mental health (i.e. resilience) have been increased in recent times. This has led to the development of a growing number of psychological treatments focusing not only in the deficit but also in protective factors and positive functioning. In addition, the potential benefits that Information and Communication Technologies can provide in the field of mental health in general, and in the treatment of mental disorders in particular, are undeniable.

Objective: This study aims to synthesize the available evidence for resiliency Internet-based training interventions in improving mental health, positive emotions, and quality of life. Data Sources: Electronic databases, reference from relevant articles, and clinical trial registries. Study authors were also contacted.

Data Extraction: Two independent reviewers worked independently in order to identify potentially relevant articles and extract study characteristics and data.

Results: 11 randomized trials were selected for this meta-analysis. The overall effects of resilience training compared to control groups at post-test were not significant; the effect size was $g=0.097$ (95%-CI: -0.117 to 0.310). In addition, looking at the theory of assessment, a potential association between the type of outcome and the effect size could be revealed ($p = 0.052$).

Conclusions: The results of the present meta-analysis showed that the overall effect of resilience training was not significant. Nonetheless, a benefit was found in the studies with a clear assessment theory, indicating there might be some promising effects. Registration Number: PROSPERO CRD42018083339

Keywords: Resilience, Theoretical adequacy, Methodological quality, online, intervention

Introduction

In recent years, there has been growing interest in the promotion of core elements of mental health such as well-being, positive functioning, or quality of life. According to the World Health Organization's definition, mental health is more than just the absence of mental illness [1]. It also involves positive emotions, adaptive ways of interpreting reality, optimism, and positive openness to the future [2]. In this vein, the focus has been progressively shifting from deficit and psychopathology models to protective factors and strengths-based approaches.

Across international literature, resilience has been pointed out as one of these protective factors that promote health and well-being, in addition to being associated with a reduction in the risk of developing mental symptoms and disorders [3, 4].

Resilience has been conceptualized in different ways throughout the research literature. This concept has evolved from a trait-oriented approach (considered an intrinsic and stable attribute) determined by a certain personality type that helps individuals to cope with stress or adversity [5, 6] to an outcome-oriented approach that suggests that resilience is a behavioral outcome that can help people to recover when facing adversities [7, 8]. Finally, most recently, a process-oriented approach has increasingly been accepted, suggesting that resilience is a changeable and multidimensional, dynamic, and variable process of adaptation [9, 10]. However, there is an even greater array of possible ways to define resilience. From the perspective of trauma, it is defined as efficacious adaptation, regardless of significant traumatic threats to personal and physical integrity [11]. Luthar [12] conceptualized resilience as a "dynamic process encompassing positive adaptation within the context of significant adversity" [12]. Similarly, a concept analysis defined resilience as the process of effectively negotiating, adapting to, or managing significant sources of stress or trauma [13].

Numerous definitions have been proposed in order to provide a conceptual framework that allows a better understanding of healthy development in spite of exposure to risk [14]. Nevertheless, due to the heterogeneity in resilience definitions, no single accepted theoretical framework or universal operationalization of the resilience concept has been established [15]. Indeed, in an attempt to clarify the concept of resilience, some authors have recently

reviewed and criticized the variety of definitions, concepts, and theories of resilience [16].

Despite the complexity of the concept, several interventions have been developed to enhance psychological resilience. Most of these interventions are based on cognitive-behavioral therapy [17], acceptance and commitment therapy [18], mindfulness-based therapy [19], and problem-solving therapy [20]. In addition, resilience-training programs have been applied to clinical and non-clinical populations using different formats and settings [21]. However, few interventions have a well-defined resilience model that can guide the mode of application of resilience interventions, and there is little consensus about the fundamental components for a program to be considered a resiliency intervention [22]. In addition, further research is needed to test the efficacy and empirical evidence of these interventions [23].

Recently, research has shown that Information and Communication Technologies (ICTs) are becoming more present in people's lives and can also contribute to enhancing happiness and well-being [24]. ICTs may be used to promote resilience, increasing the possibilities of developing strategies to prevent mental disorders and reduce the negative effects of adversity on individuals' mental health [25]. As Riva [26] pointed out, Positive Technology (the combination of Positive Psychology and ICTs) can be used to increase wellness and generate strengths and resilience in individuals, organizations, and society.

To date, only two systematic reviews [25, 27] and two meta-analyses [22, 28] have shown the efficacy of resilience interventions in adults. However, to the best of our knowledge, there are no systematic reviews or meta-analytic studies focusing on resilience interventions applied over the Internet. Thus, the primary objective of this article is to synthesize the available evidence about the effectiveness of Internet-based training interventions for improving resilience, positive emotions, and quality of life. A second aim is to analyze the methodological and theoretical adequacy of these interventions.

Methods

The Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) Statement [29] was used as a guide to carry out this meta-analysis. For the theoretical adequacy, analysis categories were selected to analyze the studies from a theoretical perspective. These categories were

defined following previous studies addressing this topic [23]. The study protocol was published in PROSPERO under registration number CRD42018083339.

Eligibility Criteria

Eligible studies were trials assessing the efficacy of online interventions designed to develop or enhance resilience in clinical and non-clinical samples. To be included in the meta-analysis, studies had to be targeted at adults or adolescents (age from 11-18 years). Eligible studies included any psychological intervention focusing on resilience in its rationale or design. The studies had to be randomized controlled trials. We included trials with no restrictions based on the type of comparison condition used (waiting list, care-as-usual; placebo; active and non-active control groups; other), the setting, theoretical basis, content or length, presence or absence of follow-ups, or publication year. We considered studies that reported generic measures of resilience at post-treatment. To be eligible for inclusion, interventions had to be delivered online over the Internet or use blended treatment modalities (Internet plus some face-to-face sessions). Studies published in English, Spanish, or German were eligible.

Information Sources

A systematic search of the peer-reviewed literature was conducted using the following electronic databases: PubMed, PsycINFO EBSCOhost, and Cochrane Central Register of Controlled Trials (CENTRAL). Additionally, Google Scholar, references from relevant articles, and clinical trial registries were searched. If the full-text was not available or data were missing or unclear, the study's authors were contacted. The terms used in the individual search were the following:

PubMed (the search was in "All Fields"):

- ("Resilien*" OR "hardiness" OR "cope" OR "coping" OR "psychological resilience")
- ("psychological intervention" OR "psychological interventions" OR "building" OR "enhance*" OR "train*" OR "educat*" OR "teach*" OR "increas*" OR "promot*" OR "prevent*" OR "intervention" OR "interventions")
- ("Internet based" OR "Online" OR "Online Therapy" OR "Internet" OR "Internet" OR "Internet treatment" OR "Web based" OR "Internet intervention" OR "Internet delivered" OR "iCBT" OR

"website" OR "computer" OR "computer based" OR "computer delivered" OR "computer administered" OR "technology" OR "technology assisted" OR "ICT" OR "computerized" OR "computerised" OR "TELEhealth" OR "eHealth" OR "mobile" OR "smartphone" OR "tablet")

The results of each individual search were combined with “and”, and the same search terms were used in the PsycINFO, EBSCOhost, and Cochrane databases.

Study Selection

In the first round of screening, two independent reviewers (AD-G, RH) independently screened eligible papers by reading titles and abstracts in order to identify potentially relevant articles. Studies that were clearly ineligible were rejected, and any conflicts warranted retrieval of a full-text copy of the article and inclusion in the next screening phase. In the second phase, reviewers independently assessed full-text versions of the relevant articles to determine final eligibility. Interrater reliability was very good (Kappa = 0.84). A total of eight criteria were established hierarchically, including whether the studies were randomized controlled trials, if their goal was to test an online application targeting resilience, the language, and the comparison with a control condition, among others. Any disagreements were resolved by consensus. If consensus was not achieved, then a third reviewer (CB) was consulted.

Data Collection

Data on the included trials were extracted in a data extraction form. Two independent researchers (RH, MF) collected information on the trial's author, year of publication, study objective, population (patients, students, workforce, other), demographics (age, gender) of participants, setting, measures, and information about the risk of bias and theoretical appropriateness. Other information extraction included the number of participants approached, the number enrolled, randomized, post-intervention means, and standard deviations. The outcomes collected were patient-reported measures of resilience, hardiness, or quality of life or well-being.

Only a single outcome was accepted within each given trial; when multiple outcomes existed, a consensus of the authors was used to determine whether the outcome measured was appropriate for inclusion. After extracting the data, we emailed the study authors to complete any missing information.

Analyses

Analyses were performed using the Comprehensive Meta-analysis Software program (CMA; Version 3.0). A random-effects model was used based on the expectation of true heterogeneity in effect sizes due to variations in the characteristics of the interventions, participants, and outcome measures. To allow the pooling of effects across different measures of similar constructs, between-group effect sizes (Hedges' g) were calculated from differences in post-intervention means and their respective standard deviations. Meta-analyses were undertaken for subgroups formed by moderators described later when the groups consisted of at least 3 comparisons. Subgroup analyses and meta-regressions were performed to identify the differences between subgroups. For each meta-analysis, the Q-test was performed to examine dispersion. Moreover, heterogeneity was computed using the I^2 statistic and its respective 95% confidence interval following the method described by Borenstein [30]. For better interpretability, the number needed to treat (NNT) was calculated based on the formula of Kraemer & Kupfer [31], indicating the number of participants who needed to receive an intervention in order to generalize one additional participant with improved resilience. Publication bias was examined using funnel plots; the Duval & Tweedi trim and fill procedures [32] and Egger's test [33].

Risk of Bias within Studies

Risk of bias was assessed for each trial independently by two team members (AD-G, MF) using Cochrane's Collaboration Tool [34]. We considered the quality of the randomization sequence generation; whether treatment arm allocation was concealed; the type and quality of blinding of participants, personnel, and outcome assessors; the degree and potential impact of missing data; the likelihood of incomplete reporting; and the potential role of conflicting interests. Studies were defined as indicating either "low", "high" or "unclear" risk of bias based on the aforementioned criteria. In cases where the intervention was explicitly intended to impact resilience and no measure of resilience was reported, we considered the study to be at high risk of selective reporting. Conflicts in judgment were resolved through discussion and consensus.

Additional Analyses

An additional aim of the present meta-analysis was to not only test the effects of online intervention studies on the resilience construct, but also to systematize a review analyzing the theoretical adequacy of each study.

Therefore, following previous studies that focused on these objectives, we developed an *ad hoc* classification framework to analyze each trial. We established three categories that were assessed using the same scale used for the risk of bias (low risk, high risk, unclear risk): 1) Presence of a background theory of resilience that sustains or guides the intervention; 2) Design of the intervention: how the theory is translated into the content of the program; 3) Construct assessment: how the intervention program is assessed with respect to what is proposed in the theoretical model (see Table 3-1 for more details about the criteria in each category). These analyses were conducted by two reviewers independently (AD-G, RH), and conflicts in judgment were resolved through discussion and consensus.

Table 3-1. Criteria for assessing the theoretical appropriateness

Item	Judgment	Description
1. There is a theory of resilience that sustains/guides the intervention	Low risk	<ul style="list-style-type: none"> - Theory focused on resilience with empirical support - AND Good quality of the empirical support for the theory
	High risk	<ul style="list-style-type: none"> - Without a background theory - OR Theory without empirical support
	Unclear risk	<ul style="list-style-type: none"> - Theory not strictly considered resilience, although related to the construct (e.g., well-being) and with empirical support - OR Resilience-centered theory with little empirical support
2. Design of the intervention (how the theory is translated into the content of the program)	Low risk	<ul style="list-style-type: none"> - The content of the intervention is described/explained - AND It includes the main components considered fundamental in the theory - AND The intervention is manualized and the theory is reflected in it
	High risk	<ul style="list-style-type: none"> - The content of the intervention is not described/explained - OR it is inadequate with regard to the theoretical basis that is supposed to support it, and it is not manualized

	Unclear risk	<ul style="list-style-type: none"> - The content of the intervention is described/explained, but it is not clear whether it adequately reflects the theory on which it is supposed to be based - OR Only includes some fundamental components, but not all of them - OR The content of the intervention is explained, but not manualized
3. Assessment (how the intervention program is assessed with regard to what is proposed in the theoretical model)	Low risk	<ul style="list-style-type: none"> - Measure (or measures) according to the theoretical model (e. g. long-term monitoring to see "resilient effect") - AND The measures cover all the key aspects of the theory - AND Use of a specific measure of resilience with empirical support
	High risk	<ul style="list-style-type: none"> - Measure not in accordance with the construct of resilience and not related either - OR Measure without empirical support
	Unclear risk	<ul style="list-style-type: none"> - Measure non-specific, but related (e. g. welfare) measure with empirical support - OR The measure does not cover all the key aspects of the theory with empirical support

Results

Study Selection

The results of our search can be seen in the flowchart presented in Figure 3-1. The three electronic databases searched generated a total of 1209 potential studies. Two additional trials were obtained through other sources. After retrieving duplicates, a total of 1010 studies were screened by title and abstract, resulting in 179 studies. Two independent researchers (RH, MF) reviewed full-text versions of these studies, providing the reasons for exclusion. Thus, the final

sample consisted of 11 randomized trials selected for this meta-analysis.

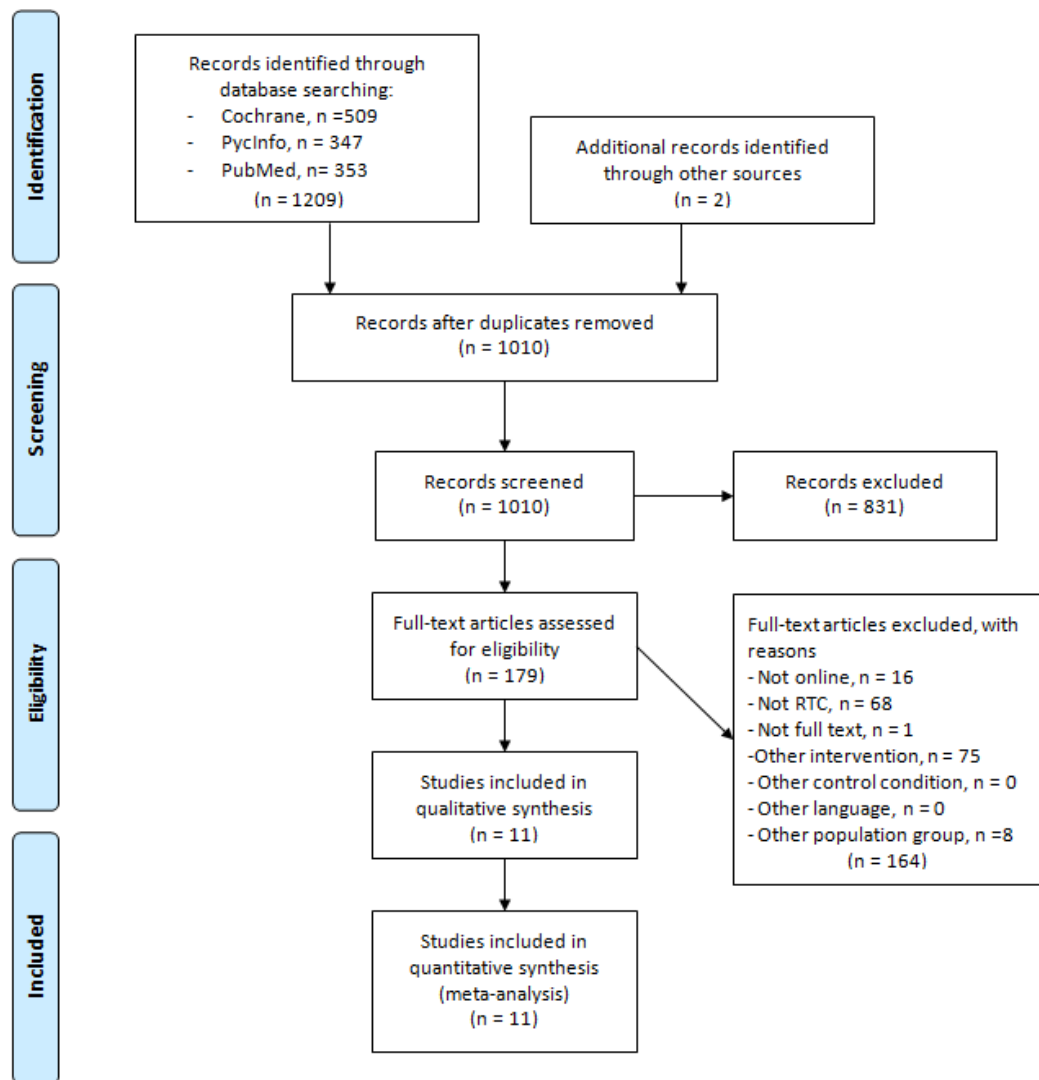


Figure 3-1. Flowchart of the process of identifying and selecting studies

Study Characteristics

Table 3-2 presents a summary of the characteristics of the trials included, as well as the theoretical base for the interventions.

In general, the purpose of the studies was to enhance resilience in diverse populations (e.g. sales manager volunteers, veterans, employees, students, etc.). Interventions varied widely in design, duration, and theoretical basis. Most of the studies did not show clear theoretical bases, drawing on broadly applicable strategies of stress management, coping, and/or cognitive behavioral therapy. A more detailed analysis of the theoretical appropriateness can be found in Figure 3-2.

	THEORY OF RESILIENCE			DESIGN OF THE INTERVENTION				ASSESSMENT			
	Clear definition of resilience	Good quality of the empirical support	RISK	The content of the intervention is described	It includes the main components for the theory	The intervention is manualized	RISK	Measure /s according to the theoretical model	The measures cover key aspects of the theory	Use of a specific measure of resilience with empirical support	RISK
Abbot et al., 2009	✓		?	✓		✓	?	✓	✓		?
Acosta et al., 2017	✓	✓	+	✓		✓	+	✓	✓	✓	+
Aikens, et al., 2014	✓		?	✓	✓	✓	?	✓	✓	✓	+
Bekki et al., 2013	✓	✓	+	✓	✓	✓	+	✓	✓	✓	+
Hoorelbeke et al., 2015	✓		?	✓	✓	✓	?	✓	✓	✓	+
Hoorelbeke & Koster, 2016	✓		?	✓	✓	✓	?	✓	✓	✓	+
Pauls et al., 2016	✓	✓	+	✓	✓	✓	+	✓	✓	✓	+
Rose et al., 2013	✓		?	✓		✓	?	✓	✓		?
De Voogd et al., 2016	✓	✓	+	✓	✓	✓	+	✓	✓		?
De Voogd, Wiers, & Salemink, 2017	✓	✓	+	✓	✓	✓	+	✓	✓		?
De Voogd et al., 2017	✓	✓	+	✓	✓	✓	+	✓	✓		?

Figure 3-2. Theoretical appropriateness of studies; + Low risk of bias; - High risk of bias; ? Unclear risk of bias

Table 3-2. Summary of characteristics of studies included

Author, Year	Purpose	Participants, age (mean), % of women	Randomized	Design	Intervention Description	Treatment Components	Definition of Resilience	Theoretical Basis	Outcomes
[17]Abbot , 2009	To enhance resilience by teaching seven skills to help improve the ability to cope with challenges and setbacks and maximize potential achievements	Sales managers volunteers, IG: 40.50 (9.45); CG: 46.00 (9.99), IG: 15.4%; CG: 11.1%	IG: 26 CG: 27	Pre, Post (10 weeks training) and follow up (10 weeks after post)	ResilienceOnline (ROL). Internet-based program: 10 weeks, online, using video, slides, Virtual Partners, graphical feedback, emails and a conference call	<ul style="list-style-type: none"> - Emotion regulation - Impulse control - Optimism - Causal analysis - Empathy - Self-efficacy - Reaching out 	A person's ability to persevere in the face of challenges, setbacks, and conflicts (Reivich & Shatte, 2002)	ROL enhances resilience by teaching users seven core skills of resilience, based on cognitive therapy:	Happiness (Authentic Happiness Inventory), Quality of Life (WHO Quality of Life - BREF), depressive, anxiety & stress symptoms (Depression Anxiety and Stress Scales), Statistics for work performance , ROL Satisfaction Questionnaire
[35]Acosta, 2017	To develop and evaluate a	Veterans with PTSD/ subthreshold PTSD and	IG: 81 TAU: 81	Baseline interview. Randomization.	Thinking Forward. Web-based program, 24 modules (12 core,	<ul style="list-style-type: none"> - Cognitive behavioral skills - Relaxation 	Resilience defined as having the coping	CBT	PTSD symptoms (CAPS), alcohol use

	web-based self-management intervention based on CBT, targeting PTSD symptoms and hazardous substance use	hazardous substance use, Age: 34.00 (8.1,) (range=22-64), 7%		Assessments at baseline, 4, 8, 12, 16 and 24 weeks	12 additional). Interactive exercises, graphs showing progress, a printable workbook containing key points and fillable copies of exercises	- Emotional centering	resources to thrive in the face of adversity		(AUDIT), drug use (DAST-10), substance use disorders (MINI), PTSD symptoms (PCL-M), Wohlbefinden (WHOQOL-BREF), Coping strategies (CSS), social support (MOS-SSS), confidence (BSCQ), expectation about future (Future Scale), change states (RTCQ), Resilience (CD-RISC)
[36]Aikens, 2014	Examine the mindfulness	Population of general employees	IG: 44 CG: 45	Baseline, post, 6 month FU	The mindfulness intervention. 7-week program	Mindfulness	Not reported	Classical mindfulness training	Mindfulness (FFMQ), Stress

	ss program to decrease employee stress and enhance resiliency and well-being	at The Dow Chemical Company (Dow), Age range= 18-65, NR			combining live, weekly hour-long virtual class meetings with accompanying online applied training. Via webinar, the Internet or cell phone. Audio exercises, pre-programmed e-mail coaching and feedback specific, and text messaging system				(PSS-14), Resilience (CD-RISC), Engagement (Shirom Vigor Scale), Lifestyle Survey questions)
[20]Bekki, 2013	Online personal resilience training program for women in stem doctoral programs	Female doctoral students in the physical sciences and engineering, Age: 27.3 (range=22-52), 100%	IG: 66 CG: 68	Pre & post (after 5-week training)	CareerWISE website. 2-week time period. Instructional modules, informational briefs, video interviews, self-tests, and practice exercises	<ul style="list-style-type: none"> - Self-efficacy - Problem-solving - Cognitive-behavioral skills training. 	Resilience is a multidimensional construct that has been applied to self-assessments of current, dispositional, or past emotions, beliefs, and behaviors and to stress levels and coping skills (Lightsey, 2006).	Grounded in psychological theory and research on personal resilience and coping in the face of stressors.	Problem-Solving Knowledge Scale, Resilience Scale, Coping Efficacy Scale, Personal Resources Scale, Confidence to Achieve STEM Landmarks Scale,

							Resilience is a dynamic process (American Psychological Association, http://www.apa.org/helpcenter/road-resilience.aspx) that has been studied by focusing on linked variables or patterns of individual adaptation (Masten, 2001).		Coping Styles, Barrier perceptions
[37]Hoorelbeke, 2015	To examine whether working memory based CCT can heighten resilience to stress and reduce rumination in the	At-risk undergraduate students (high trait rumination), IG: 20.84 (2.27); Active control: 20.45 (1.45), IG: 100%; Active control: 18.1%	IG: 25 Active control: 22	pre, post, 4 week FU	10 training sessions over 14 days, preferentially only performing one session a day. IG: Cognitive control training; Active control: visual search training	- Cognitive control training - Visual search training	Resilience, as operationalized by stress reactivity and rumination in response to a lab stressor	Working memory functioning as a way to reduce cognitive vulnerability to depression	Depressive symptomatology (BDI-II-NL), depressive and anxious symptomatology (MASQ-D30), rumination (RSS-NL-EXT), worrying

	wake of stress								(PSWQ), positive and negative affective states (PANAS), attentional control (ACS-NL), Resilience (Dutch resilience scale, RS-NL), several tasks including stress induction
[38]Hoorelbeke, 2016	To test whether Internet-delivered cognitive control training (CCT) can be used as an intervention to increase resilience to depression	Remitted depressed sample, IG: 46.12 (10.80); Active control: 47.82 (12.20), IG: 64,7%; Active control: 67,6%	IG: 34 Active control: 34		10 online sessions of the adaptive PASAT (CCT condition) or a low cognitive load training (active control condition) over a period of 2 weeks	- Cognitive control training - Low cognitive load training	Not reported	Working memory functioning as a way to reduce cognitive vulnerability to depression	Near Transfer (non adaptive PASAT), cognitive complaints (BRIEF-A), Depressive rumination (RSS), depressive symptomatology (BDI-II), maladaptive & adaptive

	n in remitted depressed (RMD) patients								emotion regulation (CERQ), disability (WHODAS), quality of life (QLDS), resilience (resilience scale), remission from depression (RDQ), life events (LTE(, treatment credibility and expectancy (CEQ)
[39]Pauls,2016	To examine whether mindfulness fosters resilience and reduces emotional exhaustion; evaluation of web-	Employees at several German companies, Age: 41,00 (11,63), 64%	IG: 57 Active control: 56	pre-post design	5 web-based session of 10 minutes each for 4 days	- Mindfulness	Resilience refers to personal resources and behavioral strategies that protect psychological well-being even under high demands	Classical mindfulness training	Mindfulness (FFMQ), Resilience (8 items questionnaires by Soucek), emotional exhaustion (subscales Maslach Burnout Inventory)

	based mindfulness intervention								
[40]Rose, 2013	To enhance resilience and reduce stress among healthy but stressed graduate students	Graduate students with no psychiatric disorder and heightened stress (PSS > 16), Age: 27.32 (3.53), 50%	IG: 34 Active control: 32	pre, post	SMART-OP (Stress Management and Resilience Training for Optimal Performance). Self-guided, 6 weekly sessions, interactive didactic video presentations, video feedback, stress briefing, feelings, thoughts and action activities, home works	<ul style="list-style-type: none"> - Educational aspects of stress management - Feelings activities address emotion/physiological regulation skills - Thoughts activities teach the user cognitive flexibility and a structured approach to realistic/logical thinking with personally relevant stressful content - Action activities teach the user to take effective 	“The ability of individuals to adapt successfully in the face of acute stress, trauma, or chronic adversity, maintaining or rapidly regaining psychological well-being and physiological homeostasis”	Unclear	Stress (PSS), perceptions of control and ability to cope with stress (SPOCS), usefulness and user experience (Stress Management Training Surveys), satisfaction with technological systems (SUS), stress induction (Trier Social Stress Test + saliva & Psychophysiological measures)

						actions to manage stress in their lives			
[41]De Voogd, 2016	Online attention bias modification training to reduce attention bias and symptoms of anxiety and depression and to increase emotional resilience in youth	Unselected adolescents, Age: 14.41 (1.20), 57.6%	340 randomized (VS = 126, DP = 128, VS Placebo = 38, DP Placebo = 48)	pre, post, 3month FU, 6 month FU, 12 month FU	Visual Search attention training: find and select single happy face in 4x4 grid of negative emotional faces; VS Placebo: find and select the only 5-petaled flower in 4x4 grid of 7-petaled flowers; Dot-probe attention training: two faces, < or > appeared; < > always at neutral face; Dot probe placebo: <> random	- Cognitive Bias Modification of Attention (CBM-A)(visual search attention training, dot-probe attention training)	not specified, only several proximal measures for "emotional resilience"	Cognitive and attentional bias	Anxiety (SCARED), Depressive symptoms (CDI); Self-esteem (RSES), perseverative negative thinking (PTQ), Test anxiety (self-report' performance motivation test for children'), social-emotional and behavioral problems (SDQ-P), Attentional Control (ACS), Stress reactivity (Cyberball)
[42]De	To test a	Adolescents	VS: 38,	Pre, Post,	Visual Search	- Visual search	not specified,		Cognitive

Voogd, Wiers, & Salemin, 2017	training aimed to modify interpretation bias to promote emotional resilience	with heightened symptoms of anxiety and/or depression, Age: 14.45 (1.53), 66.7%	VS Placebo: 32, Control: 38	FU1, FU2	attention training: find and select a single happy face in a 4x4 grid of negative emotional faces; VS Placebo: find and select the only 5-petaled flower in a 4x4 grid of 7-petaled flowers	training	only several proximal measures for "emotional resilience"	Cognitive and attentional bias	outcome measures, anxiety (SCARED), depressive symptoms (CDI), Self-esteem (RSES), Perseverative negative thinking (PTQ) social-emotional and behavioral problems (SDQ-P), Stress reactivity (responses to anagram test)
[43]De Voogd et al., 2017	To test a training aimed to modify interpretation bias to promote emotional resilience	Adolescents with heightened symptoms of anxiety or depression, Age: 15.68 (1.33), 63%	Scenario: 36, Picture-word: 44, control: 39	pre, post, 6 month FU	Scenario training: scenario paradigm, 3-line-ambiguous scenario with missing word in last sentence, word as fragment, needs to be completed;	- Cognitive Bias Modification of Interpretations (CBM-I)	not specified, only several proximal measures for "emotional resilience"	Cognitive and attentional bias	Anxiety (SCARED), depressive symptoms (CDI), interpretation bias (REC-T & SST), Stress

					<p>positive way in normal training; Scenario control: same but word made it neutral; Picture-word training: pictures of situations that could be interpreted in positive and negative ways; in training it was combined with words that gave a positive interpretation to the situation</p>				<p>reactivity (response to anagram stress task), self-esteem (RSES), worry and rumination (PTQ), social-emotional and behavioral problems (SDQ-P), cost-effectiveness (ED-5D-Y), spontaneous use of mental imagery in daily life (SUIS), evaluation)</p>
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Assessment of methodological quality

Figure 3-3 summarizes the different aspects related to the methodological quality of the studies, following the Cochrane guidelines [34]. Most of the studies provided information about random sequence generation and allocation concealment. Only one study reported high risk in the blinding of the outcome assessment. Regarding incomplete outcome data, two of the eleven studies did not include an analysis of completers. Finally, five studies provided data from all of the questionnaires administered at the beginning and end of the study, and only three studies did not perform an intention-to-treat analysis.

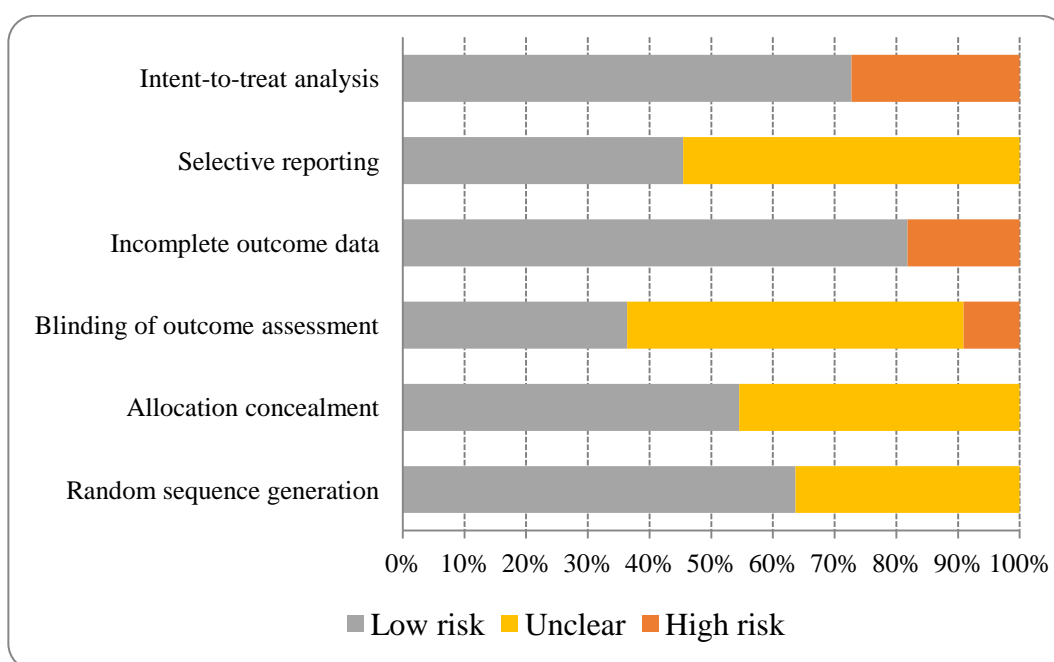


Figure 3-3. Methodological analysis of randomized controlled trials

Meta-analyses

Effects of resilience training compared to control group

The overall effects of resilience training compared to control groups at post-test were not significant; the effect size was $g=0.097$ (95%-CI: -0.117 to 0.310). This effect size correlates with a number needed to treat (NNT) of 17.86 (95%-CI: 0 to 5.75). Heterogeneity was moderate to high ($I^2 = 69.032\%$; 95%-CI: 45.06 to 82.54). The effect sizes and 95% CI for each study are presented in the forest plot (Figure 3-4). Two studies were included that compared two kinds of resilience training to a placebo group [41, 42]. Therefore, multiple comparisons from these studies were included in the same analysis, whereas these comparisons are not independent from each other. This could have affected the

heterogeneity and the pooled effect size. To examine its possible effect, we conducted an analysis with only one effect size per study; the first time with only the largest effect size per study and a second time with only the smallest effect sizes. As Table 3-3 shows, the effect sizes and heterogeneity were nearly the same in both analyses. Due to high heterogeneity, potential sources were investigated. Therefore, subsequent meta-analyses were performed, excluding the study with the highest [20] or (2) lowest [17] effect size. However, none of the described methods reduced the heterogeneity. Only excluding every study whose point estimate of effect size was outside the confidence interval of the pooled effect size had an effect. The analysis of the remaining four studies revealed a non-significant effect size of $g = 0.04$ (95%-CI: -0.16 to 0.24) with the low heterogeneity of $I^2 = 0$ (95%-CI: 0 .to 73.78). Details can be found in Table 3-3

Inspecting the funnel plot and Duval & Tweedie's trim-and-fill procedure indicated that there was no publication bias. Moreover, Egger's test did not show any indication of an asymmetric funnel plot (intercept -1.80, 95%-CI: -8.50 to 4.91, $df = 11$, $p = 0.57$). Because no study measured long-term effects, they could not be examined.

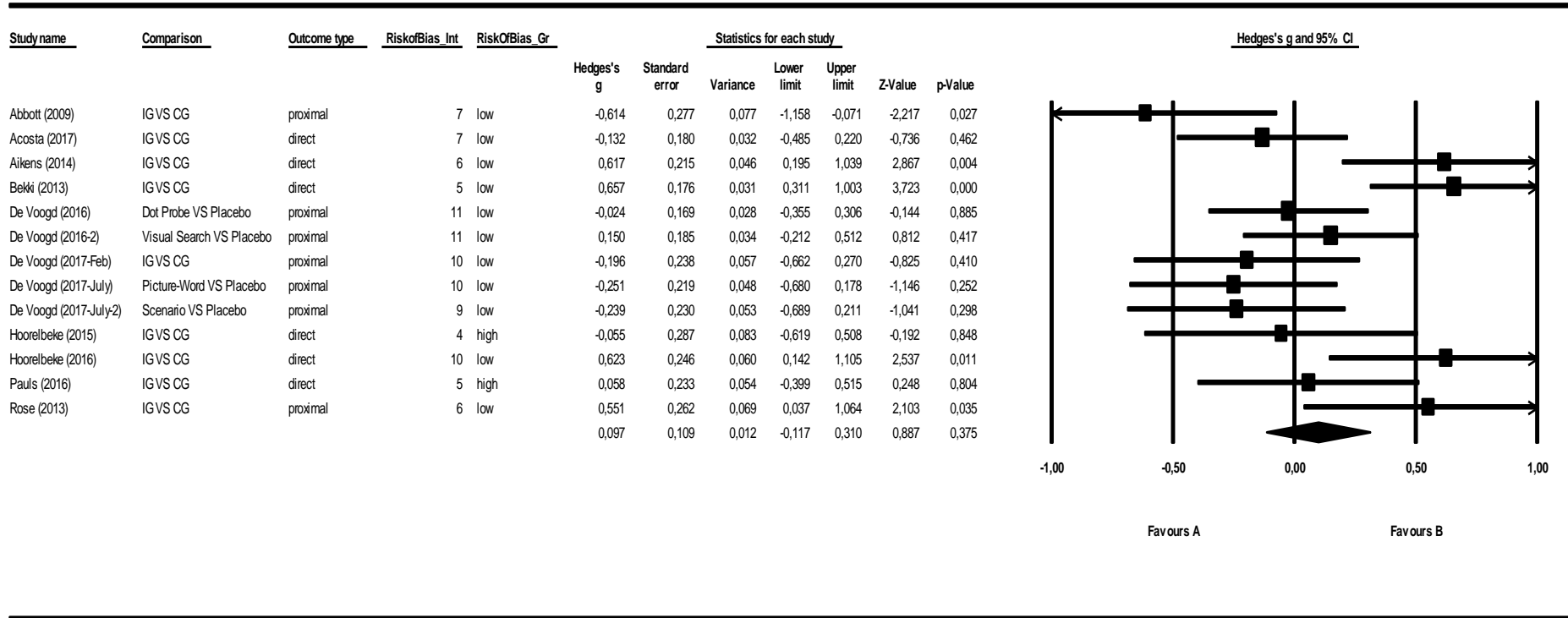


Figure 3-4. Standardized effect sizes of resilience training compared to control groups: Hedges' g

Table 3-3. Effect of resilience training compared to control groups: Hedges' g^a

	<i>n</i>	<i>g</i> (95% CI)	<i>Z</i> value	<i>I</i> ² [95%-CI]	<i>p</i> ^b	NNT [95% CI]
All studies	13	0.10 (-0.12 to 0.31)	0.89 N.S.	69.02 [45.06; 82.54]		17.86 ^c
One effect size per study (highest)	11	0.14 (-0.11 to 0.39)	1.12 N.S.	71.16 [50.04; 85.12]		12.82 ^c
One effect size per study (lowest)	11	0.12 (-0.13 to 0.37)	0.95 N.S.	72.41 [49.35; 84.97]		14.71 ^c
Removed Outlier (highest)	12	0.04 (-0.16; 0.24)	0.42 N.S.	60.67 [26.04; 79.08]		45.45 ^c
Removed Outlier (lowest)	12	0.15 (-0.06; 0.35)	1.39 N.S.	65.14 [35.56; 81.14]		11.90 ^c
Removed all outliers (point estimate outside pooled CI)	4	0.04 (-0.16; 0.24)	0.40 N.S.	0 [0; 73.78]		45.45 ^c
Subgroup analyses						
Risk of Bias					0.747	
low	11	0.11 (-0.13 to 0.35)	0.91 N.S.	73.91 [52.50; 85.67]		16.13 ^c
high	2	– ^e	– ^e	– ^e		– ^e
Theory of resilience					0.294	
unclear	5	0.25 (-0.11 to 0.61)	1.38 N.S.	76.78 [45.58; 90.44]		7.14 ^c
good	8	0.01 (-0.25 to 0.28)	0.11 N.S.	60.84 [15.08; 81.94]		166.67 ^c
Theory of intervention					0.350	

unclear	6	0.22 (-0.11 to 0.55)	1.29 N.S.	73.33 [36.14; 88.01]	8.06 ^c
good	7	0.01 (-0.27 to 0.29)	0.06 N.S.	66.42 [25.00; 84.97]	166.67 ^c
Theory of assessment					0.052
unclear	7	-0.08 (-0.34 to 0.18)	-0.60 N.S.	51.88 [0; 79.53]	— ^d
good	6	0.30 (0.02 to 0.59)	2.11 N.S.	69.43 [28.18; 86.99]	5.95 [83.33; 3.09]

CI, confidence interval; NNT, numbers needed to treat; N.S., not significant ($p > 0.05$).

^a According to the random effects model

^b The p values indicate whether the difference between the effect sizes in the subgroups is significant.

^c The 95% CI was not calculated for this NNT because the lower limit was below zero.

^d The NNT was not calculated because it was below zero.

^e No Analysis was performed because the number of comparisons was below 3

Subgroup and meta-regression analyses

A series of analyses were conducted to examine associations between the effect sizes and the characteristics of the study. There was no indication that the effect size was significantly associated with the overall Risk of Bias rating, the theoretical appropriateness of the theory of resilience, or the theoretical appropriateness of the design of the intervention. However, looking at the theory of assessment, a potential association between the type of outcome and the effect size could be revealed ($p = 0.052$). Six studies had a good theory of assessment, whereas five studies (7 comparisons) had an unclear theory of assessment. For details, see Table 3-2. Looking at the effects on a subgroup level, a significant overall effect was found in the group of studies with a high theory of assessment of $g = 0.30$ (95%-CI: 0.02 to 0.59). Studies in this subgroup showed a moderate to high heterogeneity of $I^2 = 69.43$ (95%-CI: 28.18 to 86.99). The overall effect in the group of studies with an unclear theory of assessment was non-significant ($g = -0.08$; 95%-CI: -0.34 to 0.18). Studies in this subgroup showed moderate heterogeneity of $I^2 = 51.88$ (95%-CI: 0 to 79.53). The results of the subgroup analyses are summarized in Table 3-3.

These findings are reflected in the associated meta-regression analyses with Hedges' g as the dependent variable. The analyses did not indicate a significant association between effect size and the Risk of Bias score (slope: -0.0425, 95%-CI: -0.1304 to 0.0454, $p = 0.3435$) or between the effect size and the theoretical appropriateness score (slope: -0.0111, 95%-CI: -0.2552 to 0.2329, $p = 0.9288$).

Discussion

The current difficulties experienced in the mental health field are well-known. There is a growing gap between the rates of mental disorders (especially anxiety and depression) and the budget to cover this demand. This reality points, first, to the need to improve the interventions and, second, to the need to find new methods to deliver them. In this regard, new strategies need to be developed regarding how and when psychological interventions should be implemented and which components such interventions should include. In addition, it is important to focus on the early stage of the disorders or their prevention. Therefore, resilience can be understood as an important key to achieving this goal. Resilience has been conceptualized in different ways throughout the research literature, but it is traditionally understood as a person's growth after a stressful situation or the personal resources that help to prevent the appearance of a disorder.

Regarding the delivery methods, the Internet has been shown to be an important tool for the delivery of online interventions to respond to this problematic situation by reducing costs and improving accessibility [44, 45]. However, there is a lack of information about the effectiveness of online psychological interventions focused on building resilience, and about their quality from a methodological standpoint. Moreover, given the diversity of the concept of resilience, it would also be useful to know the theoretical adequacy of the existing interventions. Therefore, taking these gaps into account, the main objective of the present paper was to study the current status of online interventions for promoting resilience and analyze their methodological and theoretical adequacy.

The results of the present meta-analysis showed that the overall effect of resilience training was not significant. Nonetheless, a benefit was found in the studies with a clear assessment theory, indicating there might be some promising effects. Several reasons can be identified to explain these findings, such as the high heterogeneity among the studies or the lack of an appropriate theory supporting the resilience program. Specifically, with regard to the theoretical

basis, several studies showed the lack of a clear concept of resilience throughout the study. Whereas some studies made an effort to clarify the basis for the study question and intervention [35, 20, 39, 41, 42, 43], others only mentioned the word “resilience” and instead described a more general mental health promotion intervention. Future studies examining resilience should be aware of the theoretical literature on this topic and try to establish a clear theoretical base, in order to achieve more conclusive results about the effectiveness of theoretically based resilience interventions.

An examination of the literature on resilience interventions revealed the widespread use of questionnaire-based assessments of resilience. Although this might be a viable option, especially in the area of online-based interventions, it should be noted that it is difficult to measure resilience in this way. The current meta-analysis showed that the studies with a high theory of assessment had better overall effects than studies with an unclear theory of assessment, possibly because of a close match between what the intervention was supposed to improve and what the study actually measured. Moreover, using a direct resilience measure could be an indicator of more theoretically based development of the interventions and studies themselves, with a clear goal stated from the beginning. However, the results of the other subgroup analysis did not show any indication that the theoretical background determined the effectiveness of the intervention. Future studies are needed to further determine what kind of intervention that helps to improve resilience. Additionally, because the concept of resilience addresses the ability to cope with stressful situations, there should be a higher proportion of studies examining resilience in the long term, directly assessing the way stressful situations were handled as opposed to the use of questionnaires focusing on general statements (e.g., CD-RISC, RS-14). Future longitudinal studies are needed to expand the current literature and do justice to the long-term process of changes in resilience.

This study has some limitations. The first is related to the low number of studies obtained, which could be due to the novelty of the field of resilience program delivery through an online format. This could be an obstacle to drawing conclusions with a high level of reliability. Second, given that the review has been conducted with three databases, some studies might have been left out. Finally, another limitation is related to the outcome measures and the heterogeneity of the resilience concept across the different studies, which can have an impact on the generalization of the current results.

In conclusion, as far as we know, although some systematic reviews of resilience have been carried out, none of them has focused on the use of the Internet to deliver resilience programs. The results obtained point to the need to continue to clarify the concept of resilience, design studies with better methodologies, and conduct more research on the effectiveness of these intervention programs in promoting resiliency.

To synthesize the available evidence about the effectiveness of Internet-based training interventions for improving resilience, positive emotions, and quality of life carry important implications for mental health policy and practice. First, these interventions are expected to create challenges for the healthcare system, focusing on the prevention of disorders and maintenance of good health instead of solely treatment of deficits. Consequently, the knowledge of the existing evidence of the efficacy of these interventions appears to be crucial to optimize the design of future studies in the field. Second, the development of these online interventions presents an opportunity to public health agencies to disseminate evidence-based psychological treatment among the population, and thus offer a more cost-effective option to reach people on a wider scale. Participation by health-care providers in these efforts is of utmost importance. Finally, findings from this meta-analysis also add information about the enormous need to clarify the concept of resilience to ensure that patients properly follow a psychological intervention for that purpose in the everyday clinical practice.

Competing interests

The authors declare that they have no competing interests.

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Chapter 4: Efficacy of a Transdiagnostic internet-based treatment for emotional disorders with a specific component to address positive affect: Study protocol for a randomized controlled trial

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Efficacy of a Transdiagnostic internet-based treatment for emotional disorders with a specific component to address positive affect: Study protocol for a randomized controlled trial

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Abstract

Background: Emotional disorders (ED) are among the most prevalent mental disorders. However, less than 50% of people suffering from ED receive the appropriate treatment. This situation has led to the development of new intervention proposals based on the transdiagnostic perspective, which tries to address the underlying processes common to ED. Most of these programs focus primarily on down-regulating negative affectivity, rather than increasing strengths and up-regulating positive affectivity. The data suggest the existence of disturbances in positive affectivity in these disorders, and so new interventions focusing on these problems are greatly needed. It is also essential to provide assistance to all the people in need. Information and Communication Technologies can be very useful. This study aims to evaluate the efficacy of a transdiagnostic Internet-based treatment for ED in a community sample. The protocol includes traditional CBT components, as well as a specific component to address positive affect. We intend to test this protocol, including this specific component or not, versus a waiting list control group. Moreover, we aim to test the differential effect of this specific component, and study the effectiveness (in terms of patients' acceptance) of using a self-applied Internet-based program. This paper presents the study protocol.

Methods: The study is a randomized controlled trial. 207 participants will be randomly assigned to: a) *Transdiagnostic Internet-based protocol (TIBP)*, b) *Transdiagnostic Internet-based protocol+positive affect component (TIBP+PA)*, or c) a Waiting List control group (WL). Primary outcomes measures will be the

BDI-II, the BAI, and the PANAS. Secondary outcomes will include diagnosis-specific measures of the principal disorder. Participants' treatment acceptance will also be measured. Participants will be assessed at pre-, post-treatment, and 3- and 12- month follow-ups. The data will be analyzed based on the Intention-to-treat principle. Per protocol analyses will also be performed.

Discussion: To the best of our knowledge, this is the first study of a transdiagnostic Internet-based treatment for ED with a specific component to up-regulate positive affectivity. This intervention could contribute to improve the efficiency and effectiveness of current treatment programs for ED, promote the dissemination of EBTs, and help to decrease the high prevalence of ED.

Trial registration: ClinicalTrial.gov: NCT02578758. Registered 15 October 2015.

Study status: Ongoing.

Keywords: Transdiagnostic, Internet, Positive affectivity, Emotional disorders, Depression, Anxiety, Emotion regulation, Randomized controlled trial.

Introduction

Lifetime prevalence estimates for emotional disorders (ED), defined as anxiety and unipolar mood disorders, are quite high (anxiety disorders, 28.8%; mood disorders, 20.8%), with comorbidity rates ranging between 40 and 80% [1]. These disorders disrupt the lives of millions of people each year, and they are one of the main causes of disability worldwide [2,3].

In the past few decades, evidence-based psychological treatments (EBTs) have been shown to be effective in the treatment of ED [4]. This development can be considered a significant advance in addressing the large worldwide treatment needs [5]. However, the scale of these treatments is not sufficient to reduce the disease burden of mental disorders [6]. Less than 50% of people suffering from ED receive adequate treatment [7], and this percentage is much lower in adolescents, older adults, people with a lower socio-economic status, and people from ethnic minorities [8].

These low levels of successful dissemination of EBTs can be explained by their costs, the duration of the treatments, and the lack of well-qualified professionals [9]. This is especially problematic in everyday clinical practice and can explain why EBTs are under-utilized [10]. It is not surprising, therefore, that this continued lack of widespread availability of EBTs has raised the need to implement innovative and even radical solutions to ensure that the aid reaches all those in need [8, 11, 12]. There is a compelling need for approaches that go beyond “one-to-one” psychotherapy (either with a patient, a family, or a group) and develop a new portfolio to administer EBTs [6].

Different EBTs targeting specific anxiety and mood disorders have been developed [13, 14, 15, 16]. Each diagnosis-specific treatment manual requires the use of separate handbooks, workbook, and protocols, and therapists must be trained in the use of each of them, which may hinder widespread dissemination of EBTs [9].

In recent years, new proposals have emerged for transdiagnostic treatments that emphasize the essential processes underlying different disorders. In the field of ED, studies emphasize that these disorders share important characteristics, and that this overlap emerges from common biological and psychological vulnerabilities [14, 17, 18]. Barlow summarizes the commonalities in the etiology of ED in the model referred to as “triple vulnerabilities”. This theory encompasses a generalized biological vulnerability (involving nonspecific genetic

contributions to the development of anxiety and negative affect), a generalized psychological vulnerability (associated with early life experiences under certain conditions), and a specific psychological vulnerability emerging from early learning [14]. There is evidence that the two generalized vulnerabilities are involved in the development and expression of the ED [19, 18].

People with ED have higher levels of neuroticism/negative affect/behavioral inhibition (N/NA/BI) [18], and they experience negative emotions more intensely and frequently [20, 21], accept emotional experiences to a lesser extent [22], associate the experience of living with more negative emotions [23], use cognitive and behavioral strategies to reduce the impact of negative emotions [24], and show intolerance to uncertainty, leading to an increase in negative affect [25]. In short, people with ED tend to react negatively to their emotions and are more likely to use maladaptive emotion regulation strategies. These strategies, in turn, increase the frequency/intensity of negative emotions. Some authors have argued that this functional relationship may be driven by neuroticism, which would be the core of the ED [26].

By contrast, the role of extraversion/positive affect/behavioral activation (E/PA/BA) in ED has also been pointed out. A meta-analysis indicated that most individuals with an ED show low levels of E/BA [27]. The data suggest that alterations in PA are observed in many disorders [28]. Low levels of PA predict the onset of depression [29], dampen positive emotions, are maladaptive, and increase the severity of the problem [30], whereas high PA is associated with better health, both physical and psychological, and greater well-being [31]. Despite the importance of disturbances in positive affectivity in ED, few studies focus on promoting PA.

Based on the transdiagnostic perspective, Barlow's team designed the Unified Protocol (UP): a transdiagnostic, emotion-focused, cognitive-behavioral treatment for ED that emphasizes the role of emotion regulation [26, 32, 9]. The UP focuses on four essential aspects that have the general purpose of down-regulating NA: addressing emotional avoidance, promoting cognitive flexibility, and facilitating exposure to avoided situations and sensations. Moreover, it places special emphasis on increasing present-focused emotional awareness. The UP has been tested, and results indicate that it is effective [33], with improvements maintained at 18-month follow-up [34]. Moreover, the effect of the UP has been shown on the two temperament dimensions of N/BI and E/BA [35].

The data suggest that a transdiagnostic treatment for ED might be more widely effective across diverse mental health problems, in other words, treatments aimed at addressing different disorders with a single protocol [36]. Some meta-analyses have been conducted on the efficacy of transdiagnostic protocols for anxiety disorders [37] and for anxiety and/or depression [38, 39, 40].

Nevertheless, these transdiagnostic protocols have focused on reducing NA, but less attention has been paid to promoting PA or modifying risk factors. As the World Health Organization's definition of mental health expresses, mental health is more than just the absence of mental illness [41]. It is not surprising, therefore, that well-being and positive functioning are considered core elements of mental health. As Southwick and Charney (2012) [42] point out, the use of procedures to promote resilience (such as positive emotions and optimism) can be useful in the treating ED and in generating protective factors. The benefits may be associated with a reduction in the risk of developing mental symptoms and disorders [43, 44]. However, as stated above, interventions that include components to up-regulate PA have been missing or very scarce in the clinical setting.

Taking all this into consideration, it is necessary to develop and test treatment components focused on enhancing protective factors and resilience and mitigating risk factors. Literature has highlighted the potential importance of positive emotionality as a treatment component [45, 46].

To date, the dominant delivery format in psychotherapy has been individual face-to-face contact; however, it is much more expensive and time-consuming than other formats, such as guided self-help and Internet-based treatments [47]. Recently, research has shown that Information and Communication Technologies (ICT) can facilitate the availability of EBTs [48, 6, 49]. Specifically, some literature suggests that the Internet can be used for the assessment and treatment of clinical conditions [50]. Internet-based treatments are interventions conducted over the Internet with more or less therapist involvement and support [51]. The evidence strongly suggests that Internet-based treatments are effective in the treatment of depression and anxiety disorders [52]. Moreover, data from meta-analyses reveal that these interventions are as efficacious as face-to-face traditional treatments [53, 54, 55].

We have developed an online psychological treatment protocol for individuals with a diagnosis of ED [56], major depression disorder (MDD),

dysthymic disorder (DD), obsessive-compulsive disorder (OCD), and four anxiety disorders: panic disorder (PD), agoraphobia (AG), generalized anxiety disorder (GAD), social anxiety disorder (SAD), anxiety disorder not otherwise specified (ADNOS), and (unipolar) mood disorder not otherwise specified (MDNOS).

This treatment protocol includes two types of components: one based on classical perspectives for down-regulating NA and the other aimed at up-regulating PA. The protocol can be applied either in its traditional format (*Transdiagnostic Internet-based Protocol –TIBP–*) or by including both of these components (*Transdiagnostic Internet-based Protocol + Positive Affect Component –TIBP+PA–*). Moreover, we have developed an adaptation of the treatment protocol that can be applied online over the Internet. We can thus reach community samples, that is, people who suffer from an ED but are not receiving primary or specialized care.

We intend to study the effect of both treatments in terms of efficacy for depressive and anxious symptomatology. Moreover, we aim to assess the effects of the specific treatment component designed for up-regulating PA. Finally, the effectiveness of the Internet-based program developed to apply the treatment protocol over the Internet with minimal support by the clinician will be studied. We hypothesize that: a) both self-applied protocol modalities (*TIBP* and *TIBP+PA*) will be more effective than the waiting list control condition in the treatment of ED; b) both interventions will result in significant improvements in depressive and anxious symptomatology at post-treatment, and these results will be maintained at 3- and 12- month follow-ups; c) the *TIBP+PA* will significantly outperform the *TIBP* group on PA measures; and d) both protocols will be well accepted, with no statistical differences between conditions. In this article, we present the study protocol.

Methods/Design

Study design

A three-armed randomized controlled trial (RCT) will be conducted. Participants will be randomly allocated to one of three conditions: a) *Transdiagnostic Internet-based protocol (TIBP)*, b) *Transdiagnostic Internet-based Protocol + Positive Affect component (TIBP+PA)*, and c) *Waiting List control condition (WL)*. For ethical reasons, participants in the control condition will be offered the possibility of receiving the treatment protocol. Block randomization will be performed within each stratum in order to ensure that all

primary diagnoses are equally represented across conditions. Measures will be taken at post-randomization, after the treatment, and at 3- and 12-month follow-ups, in order to test whether the improvements achieved during the therapy are maintained in the long term. The study flowchart is shown in Figure 4-1. The study will be conducted following the CONSORT statement (Consolidated Standards of Reporting Trials, <http://www.consort-statement.org>) [57, 58] the CONSORT-EHEALTH guidelines [59], and the SPIRIT guidelines (Standard Protocol Items: Recommendations for Interventional Trials) [60, 61].

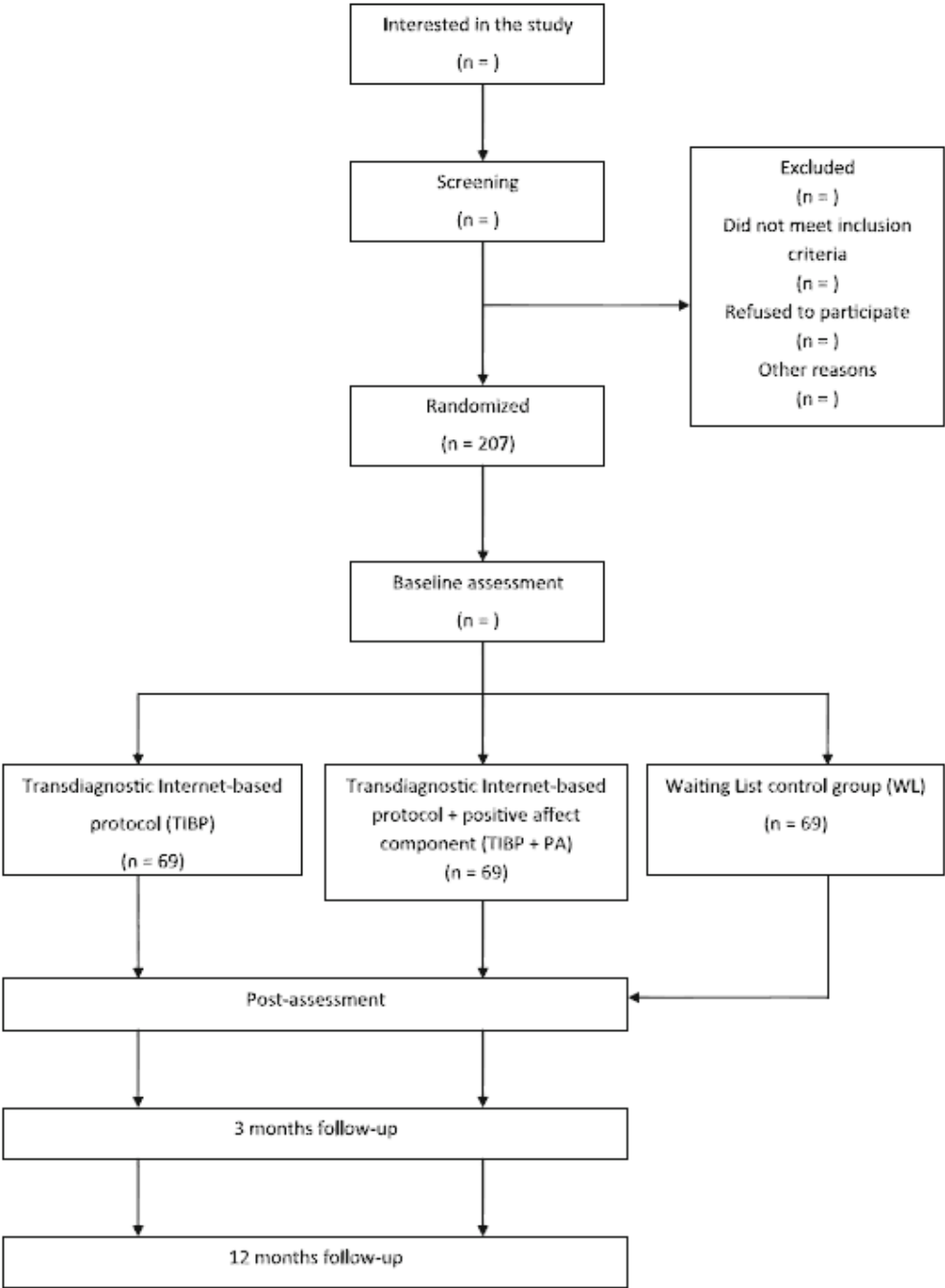


Figure 4-1. Flowchart of participants

Sample size

To determine the sample size, the effect sizes found in the literature have been considered. An RCT using the UP in a traditional face-to-face approach [33] obtained effect sizes of 0.56 for anxiety, measured with the BAI, and 1.11 for depression, measured with BDI-II. The mean effect size indicated in a recent meta-analysis [39] comparing transdiagnostic computerized cognitive-behavior therapy (CBT) to waitlist control was $g = .93$ for anxiety and $g = .88$ for depression.

Adopting a more conservative approach than those of the aforementioned studies, we assumed an effect size of 0.5 (Hedges' g), which, following Cohen [62], can be considered an effect size of medium magnitude. As our design included three experimental conditions (*TIBP*, *TIBP+PA*, *WL*), a between-groups one-way ANOVA was assumed for the statistical analyses. Therefore, calculations of the necessary sample size cannot be based on Hedges' g index for effect size, but rather on the f index [62]. Following Cohen [62], $f = 0.25$ represents an effect size of medium magnitude (and equivalent to $g = 0.5$). Thus, considering an alpha of .05 and a statistical power of .80, the total sample size required to warrant these conditions contains 159 participants (53 participants per group). To control the maximum possible loss of subjects during treatment, based on the literature about Internet-based treatments, a 30% dropout rate is expected [53, 63]. Thus, the required sample size should have 207 participants in all (69 participants per group). These calculations were accomplished with the software program *G*Power 3.1*[64].

Study population, recruitment and eligibility criteria

The clinical trial will be conducted in a community sample of patients diagnosed with the aforementioned disorders. Participants will be adult volunteers who contact us because they are interested in the study (personal visits or phone calls to the emotional disorders university clinic, emails, or leaving their data on a website specially prepared for this purpose). Potential participants will be attended to by a psychologist who will describe the study characteristics to them. All the psychologists working on this study will have at least a master's degree in Clinical Psychology, with experience in the diagnosis, psychological assessment, and application of EBTs for ED.

The psychologist will clarify any doubts, ensure that the participant has read the information about the study, and make sure that s/he has understood

the three experimental conditions. People interested in participating will sign an online informed consent and be assessed taking into account all the inclusion criteria. Inclusion and exclusion criteria are shown in Table 4-1. If the patient fulfills all the study criteria, the researcher will contact an independent researcher to implement randomization. This researcher will be unaware of the characteristics of the study.

Randomization will be performed using weighted random allocation [65] in order to take into account the clinical features (different diagnoses) and, thus, obtain a homogeneous distribution in the three experimental conditions. Participants agree to participate before finding out to which treatment they will be allocated. All participants will be free to withdraw from the treatment at any time.

Table 4-1. Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Minimal age of 18 years	Suffering from Schizophrenia, bipolar disorder, or alcohol and/or substance dependence disorder
Meeting the DSM-IV diagnostic criteria for ED	High risk of suicide
Ability to understand and read Spanish	Medical disease/condition that prevents the participant from carrying out the psychological treatment
Access to Internet at home and having an email address	Receiving another psychological treatment during the study
Providing online informed consent	An increase and/or change in the pharmacological treatment (in the case of receiving) during the study period

Ethics

The study follows the guidelines of the Declaration Helsinki and existing guidelines in Spain and the European Union for the protection of patients in clinical trials. As noted, all participants will be volunteers, and they will sign the online informed consent to form part of the study once it has been explained to them. Participants will have the possibility of withdrawing from the study at any time. The recruitment of participants will be carried out by qualified personnel from a clinical point of view. Participants allocated to the *WL* condition will be offered the opportunity to receive the *TIBP* or the *TIBP+PA* intervention after the waiting time has ended. Based on the literature, no special difficulties are expected. However, any undesired event would not only mean the participant's departure from the trial, but s/he would also be offered the possibility of receiving

psychological care at the Emotional Disorder Clinic in Universitat Jaume I, or of being referred if his/her medical condition required it.

A fundamental aspect in a project of this nature is data protection. To protect information, strategies using personal passwords and data via AES encryption (AES-256; Advanced Encryption Standard) will be used. Personal data will be replaced by codes and data, which must be collected by clinicians (e.g. age, sex, address, and phone), stored separately from other data, and only made available to researchers responsible for the study, always protecting the right to privacy.

The study has been approved by the Ethics Committee of Universitat Jaume I (Castellón, Spain). The trial was registered at clinicaltrials.gov as NCT02578758.

Interventions

We have developed a manualized protocol, based on the transdiagnostic perspective for the treatment of ED: MDD, DD, OCD, PD, AG, GAD, SAD, ADNOS and MDNOS. The treatment protocol is structured in a patient handbook and a therapist handbook [66]. The modules in each intervention protocol are described briefly in the following section.

We have adapted this protocol from classic perspectives derived from the UP [17, 9] and some strategies from Marsha Linehan's protocol [67]. The protocol includes the following core components mainly addressed to down-regulate NA: present-focused emotional awareness and acceptance, cognitive flexibility, behavioral and emotional avoidance patterns, and interoceptive and situational exposure. The protocol also includes traditional therapeutic components of evidence-based treatment for ED (Psychoeducation, Motivation for change, and Relapse prevention). In addition, in order to promote psychological strengths and enhance well-being [68], we have included a PA-regulation component based on behavioral activation strategies [69], strategies to promote pleasant and significant activities linked to values and life goals, and strategies to enhance personal strengths, positive feelings, positive cognitions, and positive behavior [70, 68]. This component also includes the Well-being Therapy (WBT) [71, 72] strategy of identifying examples of well-being and negative cognitions ("interrupting thoughts") that interfere with these moments of well-being, in order to modify these interfering cognitions. Some notions of Fredrickson's Broaden-and-Build Theory are also included to explain the mechanisms behind positive emotions [31].

Transdiagnostic Internet-based protocol (TIBP)

This intervention protocol consists of twelve more traditional modules mainly designed to down-regulate NA. Each module has specific objectives:

M1. Emotional disorders and emotion regulation. The purpose of this module is to provide information about the central role of emotion regulation in emotional disorders. Brief descriptions of the program modules, as well as videos with examples of people suffering from different ED, are also presented.

M2. Motivation for change. The objective of this module is to enhance motivation for change by recognizing that attitudes towards change can be ambivalent and that motivation fluctuates. The main objective is to analyze the advantages and disadvantages of changing, emphasize the importance of being motivated, and highlight the importance of establishing significant life goals.

M3. Understanding the role of emotions. This module provides information about the adaptive roles and functions of emotions. It also shows the three-component model of emotions.

M4. The acceptance of emotional experiences. This module focuses on the awareness and role of acceptance of emotional experiences, as well as their importance in the treatment.

M5. Practicing acceptance. The objective of this module is to continue to learn about the acceptance of emotional experiences and increase awareness of physical sensations, thoughts, emotions, and daily activities.

M6. Learning to be flexible. This module teaches participants to be more cognitively flexible in order to see life situations from different perspectives, showing

the importance of maladaptive ways of thinking and learning how to identify them in the maintenance of emotional disorders.

M7. Practicing cognitive flexibility. This module aims to teach the patients how to modify maladaptive ways of thinking. It also provides information about intrusive thoughts and how to deal with them.

M8. Emotional avoidance. The aim is to teach the patients emotion avoidance strategies that contribute to the maintenance of emotional disorders.

M9. Emotion Driven Behaviors (EDBs). The aim is for patients to learn the concept of EDBs and replace their own maladaptive EDBs with other more adaptive behaviors.

M10. Accepting and facing physical sensations. The objectives are to teach the patients the role of physical sensations in their emotional response and train them in interoceptive exposure, in order to increase tolerance and promote habituation to physical sensations.

M11. Facing emotions in the contexts where they occur. This module aims to increase tolerance to emotions and reduce avoidance behavior. The purpose is to construct exposure hierarchies to help patients to begin to face the avoided situations that contribute to the maintenance of the problem.

Transdiagnostic Internet-based protocol + positive affect component (TIBP+PA)

This intervention protocol is made up of 16 therapeutic modules. The first 12 modules have been described above in the first condition - (*TIBP*) - and the other 4 are aimed to up-regulate PA by understanding and capturing positive emotions, and training adaptive positive emotion regulation strategies. These four modules are described as follows:

M12. Learning to move on. This module focuses on the role of behavioral activation. The aim is to teach the importance of 'moving on' in acquiring a proper level of activity and involvement in life. It motivates the patient to get involved in meaningful activities and become engaged in his/her life.

M13. Learning to enjoy. This module helps the patient to see the importance of positive emotions and teaches procedures that generate positive experiences, promoting involvement in pleasant and significant activities and contact with others. This module involves enjoying positive experiences and "savoring" positive aspects of life in order to enhance wellbeing.

M14. Learning to live. This module takes a further step in enhancing PA, understanding the importance of identifying the individual's own psychological strengths, and selecting and carrying out meaningful activities linked to values and goals in life. This module provides strategies to achieve psychological well-being and resilience. The aim is to improve the individual's abilities and live a life full of purpose and meaning.

M15. Living and learning. This module focuses on developing an action plan to boost the individual's psychological strengths. It focuses on the importance of developing and enhancing one's own strengths and starting to work for life and the future.

M16. Relapse prevention (this module is the same for both conditions: (TIBP) and (TIBP+PA)). It aims to strengthen the strategies learned throughout the program, schedule future practice, and teach how to identify and cope with future high- risk situations.

Adaptation to the Web

This protocol has been adapted to a multimedia web platform (video, images, etc.) and can be applied over the Internet (<https://www.psicologiatecnologia.com/>). It is developed for optimal use on a PC or a tablet, and it allows individuals to do the modules from their home and at their own pace. The ease of use of the program has been strengthened because it presents a streamlined navigation, which allows users with less experience in handling new technologies to know where they are and how to keep moving forward at any time. The web adaptation of the protocol is the same in both conditions (TIBP and TIBP+PA), with the only difference being the inclusion or not of the modules that contain the PA-regulation component.

Duration of the program can vary among users, and participants in both treatment conditions have access to the protocol for a maximum period of 18 weeks. The program recommends working on one module for at least one entire week, and it sends messages encouraging the patient to continue to work to benefit from it. In both conditions, the modules include exercises and tasks to practice each technique and skill. Moreover, the platform is ready to welcome all participants with information about the treatment and its objectives, as well as general information and recommendations about how to benefit from it.

Regarding the assessment of patients within the program, after the “Welcome”, initial online questionnaires are presented as the pre-treatment assessment. In addition, post-module brief questionnaires to evaluate anxiety, depression, and positive/negative affect (OASIS, ODSIS, PANAS) are also filled out throughout the program. A noteworthy aspect of the program is that it allows the therapist to have access to all this information and receive an alert if the patient's condition worsens. The program includes suicide risk alarms that consist of an email to the clinical team with information about a high risk of suicide.

These alarms are generated when the system detects that the participant rated high on the suicidal ideation items. It allows the clinician to contact the patient and evaluate the actions that should be taken to protect him/her. Finally, after the treatment, the participants complete the online assessment in the post- and follow-up periods.

All the modules are sequential, which allows the participant to move through the program step by step. The web platform was designed to optimize the understanding of the modules' content. It has different multimedia elements (vignettes, videos, audios,...) that help the user to assimilate the different psychological techniques in the easiest way. The modules always follow the same structure: they start with questions related to the previous module, continue with the specific contents of the module, then propose the exercises, and finally present a series of simple self-assessment questions designed to verify whether the content presented has been understood correctly. In addition, at the end of each module, homework tasks are indicated to work on what was presented in the module. Performing these tasks helps to consolidate everything learned in the program. Participants have the opportunity to obtain printable documents (PDF) with summaries of each module.

The web platform has four complementary tools that appear on the main menu of the protocol: 1) "Home", which is the starting point from which the participant can access the other sections of the protocol; 2) "Calendar", which is a tool that allows the participant to know about pending or achieved tasks as well as his/her current point in the program; 3) "Review", which allows the participant to review the treatment modules already completed; and 4) "How am I?", which allows participants to monitor their progress through a set of graphs. It is a tool that provides feedback to participants about their evolution during the program with regard to their emotional distress (anxiety and sadness) and their positive and negative affectivity.

Support

In each of the two treatment conditions, we will provide human support and ICT support to all participants.

Human support will be provided by weekly phone calls (maximum of 5 minutes) during the treatment period in order to resolve any difficulties or doubts about the use of the online protocol, or to remind them of the importance of doing the homework tasks and reviewing the treatment contents. During these weekly

phone calls, we will also encourage participants to continue to use the protocol, and reinforce them for engaging in the treatment. At the end of the treatment period, participants will be reminded that they will be contacted again for follow-up assessments.

ICT support will consist of two weekly mobile phone text messages reminding participants of the importance of reviewing the modules and encouraging them to do the homework tasks. Some examples of these text messages are: “Hi there! Don’t hesitate to review the modules you’ve already completed if necessary. Remember, practice makes perfect!” or “Hi there! Don’t give up on your module tasks! Dedicate some time and effort to them. Remember, it’s ideal to complete one module each week”. These messages will be randomized, so that participants do not always receive the same content. A professional platform will be used to send these messages (www.trendoo.es). The online treatment also contains several multiple-choice questions about the contents seen in each module. The program immediately provides the participant with the correct feedback and a simple explanation. This aspect is repeated throughout all the treatment modules. In addition, the ICT support includes automatic e-mails with reminders to access the program when participants have not entered in the past 15 days.

Measures

Diagnostic interview

Mini International Neuropsychiatric Interview Version 5.0.0 (MINI) [73]. It is a short, structured, diagnostic psychiatric interview for DSM-IV and ICD-10 diagnoses. The MINI can be used by clinicians after a brief training session. Nonclinical interviewers should receive more intensive training. This interview has excellent inter-rater reliability ($k=.88 - 1.00$) and adequate concurrent validity with the Composite International Diagnostic Interview [74]. The MINI has been translated and validated in Spanish [75].

Primary outcomes measures

Beck Depression Inventory (BDI-II) [76]. It is one of the most widely-used questionnaires in the evaluation of depression severity. The BDI consists of 21 items, scored on a scale from 0 to 3, covering all the different symptoms of major depression disorder. The total score on this questionnaire can yield a maximum of 63 points. The instrument has shown good internal consistency ($\alpha = 0.76$ to

0.95). The Spanish version of this instrument has also shown high internal consistency ($\alpha = 0.87$) for both general and clinical populations ($\alpha = .89$) [77].

Beck Anxiety Inventory (BAI) [78]. The BAI is a 21-item symptom checklist designed to assess anxiety symptoms. Each item is scored on a 0 to 3 point severity scale, and the total scores range between 0 and 63. The internal consistency of the BAI has been found to range from .85 to .94. The Spanish version of the BAI has shown high internal consistency ($\alpha = .93$) [79].

Positive and Negative Affect Scale (PANAS) [80]. The PANAS consists of 20 items with a range from 1 (very slightly or not at all) to 5 (extremely). Respondents have to indicate the extent to which they experienced the feeling or emotion during the past few weeks. This scale evaluates two independent dimensions: PA and NA. The maximum score for each subscale is 50. The scale showed excellent internal consistency (α between .84 and .90) and convergent and discriminant validity. The Spanish version has demonstrated high internal consistency ($\alpha = 0.89$ and 0.91 for PA and NA in women, respectively, and $\alpha = 0.87$ and 0.89 for PA and NA in men, respectively) in college students [81].

Secondary outcomes measures

Diagnosis-specific measures

Depending on each participant's main diagnosis, different instruments will be implemented.

- OCD: Obsessive-Compulsive Inventory-Revised (OCI-R) [82]. The OCI-R is a short scale made up of 18 items rated from 1 to 4 to assess obsessive-compulsive symptoms. The OCI-R yields six subscales: washing, checking, ordering, obsessing, hoarding, and neutralizing. The OCI-R has good internal consistency ($\alpha = .81$ to $.93$), good to excellent test-retest reliability ($\alpha = .57$ to $.91$), good convergent validity, and a solid factor structure. The Spanish version of the OCI-R has been found to be good ($\alpha = .86$) [83].
- PD/AG: Self-Reported Panic Disorder Severity Scale (PDSS-SR) [84]. The PDSS-SR is a 7-item self-report measure of panic disorder severity. This scale assesses panic attack frequency, distress during panic attacks, severity of anticipatory anxiety, fear and avoidance of agoraphobic situations, fear and avoidance of physical sensations, and work and social impairment. The scale has shown excellent reliability ($\alpha = .917$), test-retest reliability (ICC = $.81$), and sensitivity to change. The psychometric

analysis of the Spanish version showed excellent internal consistency ($\alpha = .85$), good test-retest reliability, and adequate convergent validity [83].

- GAD: Penn State Worry Questionnaire (PSWQ) [85]. It is a questionnaire that evaluates symptoms related to GAD. The PSWQ is a 16-item self-report questionnaire that assesses the tendency to worry, as well as the intensity of the worry characteristic of GAD as an uncontrollable, generalized, and excessive experience. The PSWQ has demonstrated good internal consistency ranging from .91 to .95, and good validity and test-retest reliability. The Spanish version of the scale showed an internal consistency of .90 and a test-retest reliability of .82, as well as adequate convergent and discriminant validity [86].
- SAD: Social Interaction Anxiety Scale (SIAS) [87]. This scale is a 20-item self-report measure rated on a 5-point scale ranging from 0 (*not at all characteristic or true of me*) to 4 (*extremely characteristic of me*). It assesses cognitive, affective, and behavioral reactions in interactive social situations (symptoms related to social phobia). The SIAS has high internal consistency ($\alpha = .88$ to $.94$) and good test-retest and discriminant reliability, as well as adequate construct validity. The Spanish validation of the scale showed adequate internal consistency [88].

Personality measures

NEO-Five Factor Inventory. The NEO FFI is the short version of the NEO-PI-R [89], designed to assess the five personality dimensions through 60 items. In this study, only the subscales of neuroticism and extraversion are used. Each scale contained 12 items with a five-point Likert response format. Two-week retest reliability is uniformly high, ranging from 0.86 to 0.90 for the five scales [90], and internal consistency ranges from 0.68 to 0.86 [90]. The Spanish version of the NEO FFI has been found to be good [91].

Quality of life

EuroQol 5D (EQ-5D-Spanish version) [92] is a generic instrument for measuring health-related quality of life. It can be used in relatively healthy individuals (general population) as well as in groups of patients with different pathologies. Each individual rates his/her own health on each of the two parts of the questionnaire. In the first part, the individual must check the level corresponding to his/her state of health in each of the five domains: mobility, self-care, daily activities, pain/discomfort and anxiety/depression. Each dimension is

divided into three levels of severity (without problems, some problems or moderate problems, and severe problems), yielding a population-based preference score or societal index (SI). There are 243 possible combinations - health states -, and the SI is calculated on the basis of these health states. The index value ranges from 1 (best health state) to 0 (death), although there are negative values for the index corresponding to those health states that are rated as worse than death. In the second part of the questionnaire, the individual values his/her own health on a more general visual analogical scale (VAS), a 10 cm vertical line on which the best and worst imaginable health states score 100 and 0, respectively.

Suicidal ideation

A suicide item has been included within the ODSIS [93] with the aim of obtaining a suicide risk indicator throughout the treatment. The total score depends on this single item, and the maximum score is 4, with a range from 0 ("*absence of thoughts of suicide*") to 4 ("*thoughts of suicide all the time*").

Post-module measures

Scores on anxious and depressive symptomatology will also be obtained after each module has been completed.

Overall Anxiety Severity and Impairment Scale (OASIS) [94]. The OASIS consists of a 5-item questionnaire with a scale from 0 to 4, which measures the frequency and severity of anxiety, as well as the level of avoidance, work/academic/home interference, and social and everyday life impairment related to anxiety symptoms. The instructions tell the respondent to consider a wide range of anxiety symptoms (e.g., panic attacks, worries, flashbacks) when answering the questions, and the time frame is "during the past week". A psychometric analysis of the OASIS scale found good internal consistency ($\alpha = .80$), test-retest reliability ($k = .82$) and convergent validity for this instrument. The Spanish version of the OASIS confirmed the factorial structure and reliability and validity data obtained by the original authors (internal consistency in both populations, general and clinical ($\alpha = .0.86$ and test-retest reliability ($k = .84$) [95].

Overall Depression Severity and Impairment Scale (ODSIS) [93]. The ODSIS is a self-report measure with five items. Individuals select among five different response options ranging from 0 to 4 for each item. This scale evaluates experiences related to depression. The ODSIS measures the frequency and severity of depression, as well as the level of avoidance, work/academic/home

interference, and social and everyday life impairment related to depression symptoms. The ODSIS can also be used to assess severity and impairment associated with low mood. In the Spanish version of the ODSIS, the internal consistency has been shown to be excellent, with a Cronbach's alpha between .91 and .94 and good convergent and discriminant validity [96].

Expectation of Treatment Scale and Opinion of Treatment Scale.

The Expectation of Treatment Scale and Opinion of Treatment Scale are questionnaires adapted from Borkovec and Nau [97]. Each scale contains five items, rated from 0 (“strongly disagree”) to 10 (“strongly agree”), which cover how logical the treatment seemed, to what extent it could satisfy the patient, whether it could be used to treat other psychological problems, and its usefulness for the patient’s specific problem. The expectation scale is applied once the intervention has been explained, at the end of the "Welcome module". This scale measures the patient’s subjective expectations about the treatment. In addition, the opinion scale is administered when the patient has completed the treatment, and its aim is to assess satisfaction with the intervention. Our group has used this questionnaire in several research studies [98, 48]. The study measures and assessment times are summarized in Table 4-2.

Table 4-2. Study measures and assessment times

Measure	Aim	Time of assessment
MINI Neuropsychiatric Interview	Diagnosis	BL, Post-T and FU
PANAS	Positive and negative affect	Post-T and Post-module
BDI-II	Severity of depression	BL, Post-T and FU
BAI	Severity of anxiety	BL, Post-T and FU
OCI-R	Severity of OCD symptoms	BL, Post-T and FU
PDSS-SR	Severity of PD and agoraphobia symptoms	BL, Post-T and FU
PSWQ	Severity of GAD symptoms	BL, Post-T and FU
SIAS	Severity of SAD symptoms	BL, Post-T and FU
NEO FFI	Neuroticism and Extraversion	BL, Post-T and FU
EQ-5D	Health-related quality of life	BL, Post-T and FU
OASIS	Severity of anxiety	Post-module
ODSIS	Severity of depression	Post-module
Suicide item	Suicidal ideation	BL, Post-module, Post-T and FU
Expectation of Treatment Scale	Expectation of treatment	BL
Opinion of Treatment Scale	Opinion of treatment	Post-T

BL, Baseline; Post-T, post-treatment; FU, follow-ups, 3 and 12-month follow-ups; PANAS, Positive and Negative Affect Scale; BDI-II, Beck Depression Inventory-II; BAI, Beck Anxiety Inventory; OCI-R, Obsessive-Compulsive Inventory-Revised; PDSS-SR, Self-Reported Panic Disorder Severity Scale; PSWQ, Penn State Worry Questionnaire; SIAS, Social Interaction Anxiety Scale; NEO FFI, NEO-Five Factor Inventory; EQ-5D, EuroQoL-

5D questionnaire; OASIS, Overall Anxiety Severity and Impairment Scale; ODSIS, Overall Depression Severity and Impairment Scale.

Data Analyses

Intention-to-treat analyses and per protocol analyses will be performed, and CONSORT recommendations will be followed [99]. First, the three groups will be compared to verify that there are no significant differences among them at baseline on the outcome measures in order to confirm that they are comparable after randomization. One-way ANOVAs for continuous variables and Chi-squared tests of independence for categorical ones will be used. For the continuous outcome measures on the posttest, the homoscedasticity assumption will be assessed with the Levene test. Where this assumption is met, the usual *F*-test will be applied to compare the posttest means for the three experimental conditions. If the homoscedasticity assumption is not met, the Brown-Forsythe *F*-test will be applied. Statistically significant *F*-tests will be followed by *post hoc* comparisons. In particular, the Tukey procedure will be applied where the homoscedasticity assumption is met, and the Games-Howell procedure if this assumption is not met.

The intention-to-treat principle will be used when analyzing primary and secondary post-treatment data and data collected at the 3- and 12-month follow-ups, using mixed-effect models with full information maximum likelihood estimation. This method has been recommended due to its flexibility on repeated-measures ANOVAs in handling missing data more appropriately [100]. To complement the results of the ANOVAs and post hoc comparisons, effect sizes will be calculated by using the standardized mean difference proposed by Cohen [62]. These effect sizes will be calculated to assess both within- and between-group changes, all of them based on a pooled standard deviation.

Although per protocol analyses (completers only analysis) suffer from selection bias, they will also be conducted to help to draw conclusions about the maximum treatment efficacy in patients who comply fully with the treatment [101].

When the trial ends, the analytic methodology for the RCT will be reviewed before analyzing the data in order to select the most appropriate analytic procedures.

Discussion

This study describes a new Internet-based transdiagnostic treatment protocol for patients diagnosed with ED. One of the core aims of this study is to provide data from an RCT to evaluate the efficacy of this protocol in a community sample, compared to a waiting list group. This protocol includes the transdiagnostic cognitive-behavioral principles [17] designed for a wide range of anxiety and depressive disorders to down-regulate NA, and it also incorporates a specific treatment component to address PA. These two ways of delivering the protocol will be tested in order to explore the effect of adding a specific therapeutic component to up-regulate PA.

Moreover, the aim of the present study is to make progress in resolving some of the challenges in the field of mental health [102], specifically in understanding the necessary treatment components to modify clinical symptoms (depression and anxiety) and strengthen people's resilience, making them less vulnerable [103, 102]. The potential impact on basic personality dimensions (N/NA/BI) and (E/PA/BA) will also be studied. As Barlow suggests [103], personality dimensions may be malleable over time, and so it can be relevant to study the "malleability" of neuroticism. Likewise, the study will also examine whether it is possible to develop strategies to modify PA (extraversion). There is growing support in the literature for the claim that positive emotions promote flexible and creative thinking and play a fundamental role in the construction of psychological strengths and intellectual and social resources that can be useful in difficult situations in the future [104, 105, 106, 107]. Some studies have proposed ways to address both the assessment and treatment of PA regulation from a transdiagnostic perspective [28, 108], but further research is needed on this topic. This study aims to explore the effect of treatment components on increasing wellbeing and PA. If this is confirmed, it would certainly represent an important shift in the research, understanding, assessment, and treatment of ED. To the best of our knowledge, this is the first study of an RCT testing an online transdiagnostic treatment protocol for ED with a specific therapeutic component to directly up-regulate PA.

The data obtained with this study can be compared to results obtained in studies with face-to-face transdiagnostic protocols using benchmarking strategies [33]. In addition, the data will also be compared to transdiagnostic protocols

applied over the Internet, but without components for up-regulating PA [15, 109, 110, 111, 112, 113].

The objective of establishing action strategies to improve access to EBTs should also be taken into consideration, as well as the goal of providing psychological support to all those in need [5]. Undoubtedly, we are witnessing the beginning of a new era in the field of psychological treatments. They have already gone beyond traditional EBTs, and now it is possible to manage these online protocols with good results [53]. The use of technology and the Internet can help to disseminate and increase the access to these interventions.

Finally, we will test the effectiveness of the application of this Internet-based program with minimal support from the clinician, and the acceptability of this online program in patients from a community sample.

We are aware that this study has limitations. One of the most important is the different number of modules in the two protocols. We tried to control this by giving all the participants equal time and allowing them to use the program as much as they like throughout the whole process. However, in order to test the potential additional impact of the positive psychology component, it seemed necessary to compare it to the traditional transdiagnostic protocol. If the new component is found to have any effect, future research should be carried out to show that this effect is not simply due to the larger number of modules in the protocol.

There are further limitations. For example, dropout rates are expected to be high (around 30%) [53, 63]. To minimize this problem, human and ICT support will be provided. In addition, another limitation may be recruitment difficulties, to the extent that people still do not have access to the Internet at home, or they have negative attitudes towards Internet interventions.

In summary, this study aims to contribute to the literature on the efficacy of transdiagnostic approaches to ED in general, and it more specifically seeks to explore the possible impact of specific component designed to up-regulate positive affect. Despite its limitations, if positive results are achieved, they will have a clear impact on the design and application of future transdiagnostic treatment protocols for ED, as a way to more effectively address the temperament vulnerabilities, that is, the core aspects of these disorders [103].

LIST OF ABBREVIATIONS

ED: Emotional disorders

EBTs: Evidence-based psychological treatments

N/NA/BI: Neuroticism/Negative Affect/Behavioral Inhibition

E/PA/BA: Extraversion/Positive Affect/Behavioral Activation

UP: Unified Protocol

MDD: Major Depression Disorder

DD: Dysthymia

OCD: Obsessive-compulsive Disorder

PD: Panic Disorder

AG: Agoraphobia

GAD: Generalized Anxiety Disorder

SAD: Social Anxiety Disorder

ADNOS: Anxiety Disorder Not Otherwise Specified

MDNOS: Mood Disorder Not Otherwise Specified

TIBP: Transdiagnostic Internet-Based Protocol

TIBP+PA: Transdiagnostic Internet-Based Protocol + Positive Affect Component

RCT: Randomized Controlled Trial

WL: Waiting List

CBT: Cognitive Behavior Therapy

ANOVA: Analysis of variance

BAI: Beck Anxiety Inventory

BDI-II: Beck Depression Inventory-II

DSM-IV: Diagnostic and Statistical Manual of mental disorders, fourth text

AES: Advanced Encryption Standard

WBT: Well-Being Therapy

EDBs: Emotion Driven Behaviors

OASIS: Overall Anxiety and Impairment Scale

ODSIS: Overall Depression and Impairment Scale

PANAS: Positive and Negative Affect Schedule

ICT: Information and Communication Technologies

MINI: Mini-International Neuropsychiatric Interview

ICD-10: International Classification of Diseases, tenth edition

OCI-R: Obsessive-Compulsive Inventory-Revised

PDSS-SR: Self-Reported Panic Disorder Severity Scale

PSWQ: Pen State Worry Questionnaire

SIAS: Social Interaction Anxiety Inventory

NEO-FFI: NEO Five Factor Inventory

EQ-5D: EuroQol-5D questionnaire

SI: Social Index

VAS: Visual Analogical Scale

CONSORT: Consolidated Standards Of Reporting Trials

BL: Baseline

POST-T: Post-Treatment

FU: Follow-Ups

DECLARATIONS

Ethics approval and consent to participate

The study follows the guidelines of the Declaration Helsinki and existing guidelines in Spain and the European Union for the protection of patients in clinical trials. All participants interested in participating signed an informed consent form. The study has been approved by the Ethics Committee of Universitat Jaume I (Castellón, Spain) (October, 2015). The trial was registered at ClinicalTrial.gov as NCT02578758.

Consent for publication

“Not applicable” in this section.

Availability of data and material

It is not possible to share the data because the study is in progress. We are now at the stage of data recruitment.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

AD-G drafted the manuscript with important contributions from CB and AG-P. AD-G, in collaboration with CB and AG-P, designed the study and participated in each of its phases. CB and AG-P designed the traditional version of the transdiagnostic protocol and carried out the Internet-based adaptation with important contributions by RB, AG-R, and JF-A. All authors participated in the review and revision of the manuscript and have approved the final manuscript to be published.

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Chapter 5: Positive affect regulation in an online transdiagnostic protocol for emotional disorders: a randomized controlled trial

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Positive affect regulation in an online transdiagnostic protocol for emotional disorders: a randomized controlled trial

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Abstract

Introduction. Emotional disorders (ED) are among the most prevalent mental disorders, with comorbidity rates ranging between 40 and 80%. In the past few decades, evidence-based psychological treatments have been shown to be effective in the treatment of ED. However, the scale of these treatments is not sufficient to reduce the disease burden of mental disorders. It is therefore essential to implement innovative solutions to achieve a successful dissemination of psychological treatment protocols, and in this regard, the use of Information and Communication Technologies like the Internet can be very useful. Furthermore, the literature suggests that not everyone suffering from ED receives the appropriate treatment, and that these interventions do not reach everyone in need. This situation has led to the development of new intervention proposals based on the transdiagnostic perspective, which tries to address the underlying processes common to ED. Most of these transdiagnostic interventions focus primarily on down-regulating negative affectivity, and less attention has been paid to strengths and the up-regulation of positive affectivity (PA), despite its importance for well-being and mental health.

Objective. This study presents a Randomized Controlled Trial evaluating the efficacy in a community sample of a transdiagnostic Internet-based treatment for ED that includes traditional cognitive-behavioral therapy components and a specific component to address PA.

Method. Participants were randomly assigned to a) a Transdiagnostic Internet-based protocol (TIBP), b) a Transdiagnostic Internet-based protocol + positive affect component (TIBP + PA), or c) a Waiting List control group (WL). Data on depression, anxiety, and positive and negative affectivity before and after treatment were analyzed.

Results. Within-group comparisons indicated significant pre-post reductions in the two experimental conditions. In the TIBP+PA condition, effect sizes were large on all the primary outcomes, whereas the TIBP condition obtained large effect sizes for BDI-II and PANAS-, and medium effect sizes for BAI and PANAS+. Between-group comparisons revealed that participants who received the treatment (with and without the specific component to up-regulate positive affect) scored better at post-treatment, compared to the WL group. Although there were no significant differences between the two intervention groups on the PA measure, effect sizes were consistently larger in the TIBP + PA condition, compared to the standard transdiagnostic protocol.

Discussion. This study aims to contribute to the literature on the efficacy of transdiagnostic approaches to emotional disorders in general, and, more specifically, it explores the possible impact of a specific component designed to up-regulate positive affect. Combining a transdiagnostic approach with an online therapy format and adding a specific component for positive affect may help to achieve a clear impact on the design and application of future transdiagnostic treatment protocols for emotional disorders, in order to more effectively address the temperament vulnerabilities, that is, the core aspects of these disorders.

Keywords: Transdiagnostic, Internet, Positive affectivity, Emotional disorders, Depression, Anxiety, Emotion regulation, Randomized controlled trial.

Introduction

The estimated lifetime prevalence rates for emotional disorders (ED) (anxiety, mood, and related disorders) are high (28.8 % for anxiety disorders, and 20.8 for mood disorders), with a 46.4% lifetime prevalence of any disorder (Kessler, Berglund, Demler, Jin, Merikangas, & Walters, 2005). In addition, the co-occurrence of multiple emotional disorders, that is, comorbidity, has also been found to be elevated, with studies showing that more than 40% of people suffering from one diagnosis also met the diagnostic criteria for a second disorder over a 12-month period (Kessler, Chiu, Demler, Merikangas, & Walters, 2005).

In recent years, research has focused on demonstrating that evidence-based psychological treatments (EBTs) (i.e. interventions with strong evidence on their behalf) are effective in the treatment of ED (Nathan & Gorman, 2016). This development has been considered a remarkable advance in targeting many psychological disorders in children, adolescents, and adults (Weisz & Kazdin, 2010). However, despite the large and consistent scale of these treatments, little success has been achieved in decreasing the prevalence and incidence of mental illness, and only a small proportion of people in need actually receive adequate psychological treatment (Kazdin & Blase, 2011). In addition, disseminating EBTs has become a real challenge due to their cost, the duration of the treatments, and the lack of well-qualified professionals (Ellard et al., 2010), which can explain why EBTs are under-utilized in clinical practice settings (McHugh & Barlow, 2010).

Motivated by the continued lack of widespread availability of EBTs, new innovative and even radical solutions have emerged to contribute to further reducing the disease burden of mental disorders (Emmelkamp et al., 2014), and a new portfolio for delivering EBTs has been proposed (Kazdin & Blase, 2011).

The development of these EBTs has been accompanied by an increasing proliferation of diagnosis-specific treatment manuals with separate handbooks, workbooks, and protocols that may hamper efforts to achieve widespread dissemination of EBTs (Ellard et al., 2010). Therefore, it is not surprising that evidence-based approaches have changed the focus from distinct diagnostic categories (i.e., disorder-based approaches) to relevant processes of change (i.e., trait-based approaches) (Emmelkamp et al., 2014). Limitations associated with categorical approaches to diagnostic classification are well recognized, and new empirically supported common dimensions across sets of disorder-specific

criteria have been adopted (Brown & Barlow, 2009). Furthermore, there is significant evidence that dimensional approaches produce more reliable and valid diagnoses (Markon, Chmielewski, & Miller, 2011) and represent a move away from the extreme diagnostic splitting evident in official nosologies for mental disorders, such as the Diagnostic and Statistical Manual of Mental Disorders (DSM) or the International Classification of Diseases (ICD) (Ellard et al., 2010).

In this regard, transdiagnostic approaches have emerged to provide answers to the common characteristics in cognitive, behavioral, emotional, and other emotional dysregulation areas underlying different ED, namely the biological and psychological vulnerabilities shared by different mental disorders (Barlow, Allen, & Choate, 2004; Brown & Barlow, 2009). With regard to transdiagnostic processes or cross-over features that are common to different ED, studies have been pointed out intolerance of uncertainty (Boswell, Thompson-Hollands, Farchione, & Barlow, 2013; Einstein, 2014), anxiety sensitivity (Paulus, Talkovsky, Heggeness, & Norton, 2015), attention biases (Mathews & MacLeod, 2005), or distress tolerance (Zvolensky, Vujanovic, Bernstein, & Leyro, 2010), among other transdiagnostic factors. In addition, maladaptive emotion regulation strategies have been suggested as potential explanatory factors underlying the comorbidity across ED (Mennin, Holaway, Fresco, Moore, & Heimberg, 2007).

Regarding the temperamental vulnerabilities, neuroticism has been identified as one of the core factors involved in the development of ED (Weinstock & Whisman, 2006). Thus, people suffering from ED have higher levels of neuroticism/negative affect/behavioral inhibition (N/NA/BI) (Brown & Barlow, 2009), and they experience negative emotions more intensely and frequently (Campbell-Sills, Barlow, Brown, & Hofmann, 2006). By contrast, the dimension of positive emotionality, extraversion/positive affect/behavioral activation (E/PA/BA) has also been observed in many disorders, suggesting that people with an ED show low levels of E/BA (Kotov, Gamez, Schmidt, & Watson, 2010), which can predict the onset of depression (Lopez & Snyder, 2009) and increase the severity of the problem (Gilbert, Nolen-Hoeksema, & Gruber, 2013). Despite the importance of positive affect in health and wellbeing, there is limited research on promoting PA, and so more research is needed in this area.

In response to transdiagnostic approaches, several transdiagnostic treatments have been developed to provide patients with a set of skills geared specifically toward the common vulnerabilities (Sauer-Zavala, Cassiello-Robbins,

Ametaj, Wilner, & Pagan, 2018). One example of these treatments is the Unified Protocol (UP) (Barlow et al., 2004), which was developed to be applicable across different ED and represented a significant shift toward transdiagnostic psychological treatments for ED (Norton & Paulus, 2016). The UP focused on the core principles of traditional cognitive-behavioral treatment (CBT), including an emphasis on emotional avoidance, cognitive flexibility, and exposure to avoided situations and sensations, which are all considered essential aspects of down-regulating negative affect (Ellard et al., 2010). The UP has been tested, and results indicate that it is effective in reducing negative affect (Farchione et al., 2012), with improvements maintained at 18-month follow-up (Bullis et al., 2014). Furthermore, the effect of the UP has been shown on the two temperament dimensions of N/BI and E/BA (Carl, Gallagher, et al., 2014).

Existing transdiagnostic treatments have demonstrated their efficacy in open (Dear et al., 2011; Ellard et al., 2010; Mcevoy, Nathan, & Norton, 2009) and randomized controlled trials (Erickson, Janeck, & Tallman, 2007; Norton & Barrera, 2012; Titov, Andrews, Johnston, Robinson, & Spence, 2010). In addition, some meta-analyses have been conducted on the efficacy of transdiagnostic protocols for anxiety disorders (Reinholt & Krogh, 2014) and for anxiety and/or depression (Newby, McKinnon, Kuyken, Gilbody, & Dalgleish, 2015; Newby, Twomey, Yuan Li, & Andrews, 2016; Păsărelu, Andersson, Bergman Nordgren, & Dobrean, 2017). Moreover, in comparison with diagnosis-specific CBT for primary anxiety disorder diagnoses, statistically equivalent efficacy has been found (Newby, Mewton, & Andrews, 2016), as well as potentially higher efficacy in reducing comorbid anxiety (Ellard et al., 2010; Norton et al., 2013) and comorbid depression (Norton, Hayes, & Hope, 2004; Talkovsky, Green, Osegueda, & Norton, 2016). The data suggest that a transdiagnostic treatment for ED might be more widely effective across a diverse range of mental disorders, addressing different disorders with a single protocol (Clark & Taylor, 2009).

Despite the recent upsurge in transdiagnostic treatments for ED, most of these protocols have focused on reducing NA. They have addressed core psychopathological deficits in the way patients experience and respond to negative emotions (Sauer-Zavala et al., 2017). However, less attention has been paid to positive emotions, promoting PA, or modifying risk factors. In addition to being involved in the symptomatology of ED, positive emotionality is considered a core element of mental health, showing beneficial, generalized effects on

health and functioning (Dockray & Steptoe, 2010; Tugade, & Fredrickson, 2004). Furthermore, the use of procedures to optimize positive emotionality in the treatment of ED promises to enhance long-term recovery and resilience, in addition to promoting acute symptom reduction (Ehrenreich et al., 2007). Nevertheless, as mentioned above, transdiagnostic treatments that include components to up-regulate PA have been missing or very scarce in the clinical setting. Based on the literature that highlights the potential importance of positive emotionality as a treatment component (Bolier et al., 2013; Roepke & Seligman, 2016; Titov et al., 2011; Carl et al., 2013), it is necessary to develop and test treatment components focused on enhancing protective factors and resilience (such as positive emotions and optimism) and mitigating risk factors.

As mentioned above, there are many models for delivering interventions in novel ways that can be scaled up to reach large numbers of people in need (Kazdin & Blase, 2011; Kazdin & Rabbitt, 2013). In this regard, Information and Communication Technologies (ICT) play an important role and can facilitate the availability of EBTs (Botella et al., 2009; Kazdin & Blase, 2011; Kazdin, 2015). Specifically, the Internet is used for the assessment and treatment of clinical conditions, and it has been established as a useful and effective tool for delivering psychological treatments to treat several psychological disorders (Andersson, 2016; Hedman, Ljotsson, & Lindefors, 2012; Peñate & Fumero, 2016). Internet-based treatments can be defined as interventions conducted over the Internet with more or less therapist involvement and human support (personal, by telephone, email or chat) (Andersson, 2009). In the field of ED, the evidence strongly suggests that Internet-based treatments are effective in the treatment of depression and anxiety disorders (Andersson & Cuijpers, 2009). Moreover, some meta-analyses reveal that these interventions are as efficacious as face-to-face traditional treatments (Andrews, Cuijpers, Craske, McEvoy, & Titov, 2010; Cuijpers et al., 2011; Cuijpers, van Straten, Warmerdam, & Andersson, 2009).

The purpose of the current study is to test the efficacy of an online psychological treatment protocol for individuals from a community sample with one or more diagnosis of ED: major depression disorder (MDD), dysthymic disorder (DD), obsessive-compulsive disorder (OCD), and four anxiety disorders: panic disorder (PD), agoraphobia (AG), generalized anxiety disorder (GAD), social anxiety disorder (SAD), anxiety disorder not otherwise specified (ADNOS), and (unipolar) mood disorder not otherwise specified (MDNOS) (American

Psychological Association., 2000). Rather than focusing solely on NA, the treatment protocol includes two types of components: one based on classical perspectives for down-regulating NA and the other aimed at up-regulating PA. The protocol can be applied either in its traditional format (Transdiagnostic Internet-based Protocol –TIBP–) or by including both of these components (Transdiagnostic Internet-based Protocol + Positive Affect Component – TIBP + PA–).

To the best of our knowledge, no published randomized controlled trial (RCT) has tested the efficacy of a transdiagnostic Internet-based treatment for emotional disorders with a specific component to address positive affect regulation. Therefore, the aim of this study is to investigate the effectiveness of this transdiagnostic protocol for depression and anxiety disorders, with and without the specific component to up-regulate positive affect, versus a waiting list control group. A secondary aim is to test the differential effect of the specific treatment component designed to up-regulate PA. Finally, the effectiveness (in terms of patients' acceptance) of the Internet-based program developed to apply the treatment protocol over the Internet with minimal support by the clinician is studied.

Methods/Design

Study design

This study was a three-armed RCT in which participants were randomly allocated to one of three conditions: 1) *Transdiagnostic Internet-based protocol (TIBP)*, 2) *Transdiagnostic Internet-based protocol + Positive Affect component (TIBP + PA)*, and 3) *Waiting List control condition (WL)*. For ethical reasons, participants in the control condition were offered the possibility of receiving the treatment protocol after spending time on the WL (16 weeks), thus leaving no control group for the follow-up measurements. Block randomization was performed within each stratum in order to ensure that all primary diagnoses were equally represented across conditions. The trial was registered at ClinicalTrial.gov as NCT02578758 on October 16, 2015. The study received approval from the Ethics Committee of Universitat Jaume I (Castellón, Spain) (5 May 2016), and it was conducted in compliance with the study protocol, following the CONSORT statement (Consolidated Standards of Reporting Trials, <http://www.consort-statement.org>) (Moher, Schulz, & Altman, 2001; Moher et al., 2010), the CONSORT-EHEALTH guidelines (Eysenbach, 2011), and the

SPIRIT guidelines (Standard Protocol Items: Recommendations for Interventional Trials) (Chan, Tetzlaff, Altman, et al., 2013) (Chan, Tetzlaff, Gøtzsche, et al., 2013). Details of the study protocol have been reported elsewhere (Díaz-García et al., 2017).

Sample size

Different effect sizes found in the literature based on the transdiagnostic perspective of ED were considered to estimate the study power in this study. An RCT using the UP in a traditional face-to-face approach that obtained effect sizes of 0.56 for anxiety (measured with the BAI) and 1.11 for depression (measured with BDI-II) was considered (Farchione et al., 2012). In addition, the mean effect size indicated in a recent meta-analysis comparing transdiagnostic computerized cognitive-behavior therapy to WL ($g = .93$ for anxiety and $g = .88$ for depression) was also taken into account (Newby, Twomey, et al., 2016). Adopting a conservative approach, an effect size of 0.5 (effect size of medium magnitude (Cohen, 1988) was assumed. Considering an alpha of .05 and a statistical power of .80, the total sample size required to warrant these conditions consists of 159 participants (53 participants per group). Finally, to control the maximum possible loss of subjects during treatment, a 30% dropout rate was expected (Andrews, Cuijpers, Craske, McEvoy, & Titov, 2010; van Ballegooijen et al., 2014), and so a total sample size of 207 participants was required. These calculations were performed with the software program *G*Power 3.1* (Faul, Erdfelder, Lang, & Buchner, 2007) and published in the study protocol (Díaz-García et al., 2017). A total of 216 participants could be included in the recruitment.

Study population, recruitment and eligibility criteria

The clinical trial was conducted in a community sample of patients diagnosed with one or more of the aforementioned disorders. Participants were adult volunteers interested in participating in the study who made contact by telephone, personal visits to the emotional disorders university clinic, emails, or by leaving their data on a website specially prepared for this purpose (see Appendix A). Potential participants were attended to by the clinical team, in order to explain the study characteristics (i.e. study design, treatment length, or treatment rationale), clarify any doubts, and ensure that the participant had read and understood all the information about the study. All the psychologists working on this study had at least a master's degree in Clinical Psychology, with experience in the diagnosis, psychological assessment, and application of EBTs

for ED. The clinical team contacted participants by telephone. People interested in participating signed the online informed consent form and were assessed taking into account all the inclusion criteria. The inclusion criteria were: a) being at least 18 years old; b) meeting the DSM-IV diagnostic criteria for ED; c) having the ability to understand and read Spanish; d) having access to the Internet and an email address; e) providing online informed consent (see

Appendix B). The exclusion criteria were: a) suffering from schizophrenia, bipolar disorder, or alcohol and/or substance dependence disorder; b) presence of high risk of suicide; c) presence of medical disease/condition that prevents the participant from carrying out the psychological treatment; d) receiving another psychological treatment during the study. Receiving pharmacological treatment was not an exclusion criterion, but any increase and/or change in the medication (in the case of receiving) during the study period implied the participant's exclusion from subsequent analyses. Participants who fulfilled all the study criteria were randomized to one of the three experimental conditions by an independent researcher. This researcher was unaware of the characteristics of the study and had no clinical involvement in the trial or access to the study data. Randomization was performed using weighted random allocation (Altman et al., 2001) in order to take into account the clinical features (different diagnoses) and, thus, obtain a homogeneous distribution in the three experimental conditions. Participants agreed to participate before finding out to which treatment they were allocated. All participants were free to withdraw from the treatment at any time. Access and participation in the study did not involve payment in any case.

The transdiagnostic Interventions

The treatment protocol is based on the transdiagnostic perspective derived from the UP (Ellard et al., 2010; Barlow et al., 2004) and some strategies from Marsha Linehan's protocol (Linehan, 1993). Initially, a manualized protocol was developed and structured in a patient and therapist handbook (Botella C, García-Palacios A, Quero S, Baños R. A Transdiagnostic Treatment for Emotion Disorders: Manualized Treatment Protocol, unpublished). Later, the protocol was adapted to a multimedia web platform (videos, vignettes, audios, images, etc.) to be completely self-applied via the Internet (<https://www.psicologiytecnologia.com/>) through a PC or a tablet. The ease of use of the program has been strengthened because it presents a linear navigation in order to optimize the treatment structure and make the treatment easier and more attractive to the participants. In addition, the program allows participants with less experience in handling new technologies to know where they are and how to keep moving forward at any time.

The program includes both an assessment protocol and a treatment protocol that includes core components, mainly designed to down-regulate NA (present-focused emotional awareness and acceptance, cognitive flexibility, behavioral and emotional avoidance patterns, and interoceptive and situational

exposure) and a PA-regulation component to promote psychological strengths and enhance well-being (Sin & Lyubomirsky, 2009). The latter component is based mainly on behavioral activation strategies (Lejuez et al., 2001), strategies to promote pleasant and significant activities linked to values and life goals, and strategies to enhance personal strengths, positive feelings, positive cognitions, and positive behavior (Sin & Lyubomirsky, 2009; Seligman & Csikszentmihalyi, 2000). Furthermore, Well-being Therapy (WBT) strategies (Fava, 1999; Fava & Ruini, 2003) and some concepts from Fredrickson's Broaden-and-Build Theory (Fredrickson, 2001) are also included in the program. The protocol also includes traditional therapeutic components of evidence-based treatment for ED (Psychoeducation, Motivation for change, and Relapse prevention). All the treatment components were developed through two self-applied protocol modalities (TIBP and TIBP + PA) with 12 and 16 modules, respectively, and with the only difference being the inclusion or not of the modules that contain the PA-regulation component. The modules in each intervention protocol are described briefly elsewhere (Díaz-García et al., 2017).

The protocol first sought to provide information about emotional disorders and the central role of emotion regulation in these disorders (module 1). Then participants were encouraged to analyze the advantages and disadvantages of changing, emphasizing the importance of being motivated and highlighting the importance of establishing a set of specific and significant life goals (module 2). The adaptive role and functions of emotions, as well as the three-component model of emotions, were presented in the following module (module 3). Participants' awareness of their emotional experiences and a set of mindfulness exercises were addressed in the next two modules (module 4 and 5). The next modules (6 and 7) presented the role of maladaptive ways of thinking and how to deal with them by practicing cognitive flexibility. The emotional avoidance concept (module 8) as an example of emotion-driven behavior (module 9) and the opposite action as a first attempt to practice exposure were presented in the next modules. Module 10 and 11 were entirely dedicated to training participants in interoceptive and situational exposure, respectively. The role of behavioral activation and the importance of "moving on" to get involved in meaningful activities were presented in the following module (module 12). Module 13 was designed to teach procedures that generate positive experiences, promoting involvement in pleasant and significant activities and contact with others, and "savoring" positive aspects of life. The next modules were aimed to identify the

individual's own psychological strengths and provide strategies to achieve psychological well-being and resilience (module 14), and to develop and enhance one's own strengths and start working for life and the future (module 15). Finally, participants were asked to review the strategies learned throughout the entire program and identify and schedule a relapse prevention plan for the future (module 16). Modules 1 to 11 are traditional modules mainly designed to down-regulate NA (included in the TIBP condition), whereas modules 12 to 15 are designed to up-regulate PA (included in the TIBP + PA condition) by understanding and capturing positive emotions, and training adaptive positive emotion regulation strategies. The last module (module 16: "Relapse prevention") is the same for both conditions: TIBP and TIBP + PA.

The duration of the program can vary among users, and participants in both treatment conditions had access to the protocol for a maximum period of 18 weeks. At the beginning of the treatment, participants were encouraged to complete one module per week and the associated homework tasks. Moreover, the program sent weekly messages to the patient to remind him/her of the need to continue to work in order to benefit from it. A professional platform was used to send these messages (www.trendoo.es). The program also sent automatic e-mails with reminders to access the modules when participants had not entered in the past 15 days. The web platform has four complementary tools that appear on the main menu of the protocol (shown in **¡Error! La autoreferencia al marcador no es válida.**). In addition to this ICT support, human support was also provided through weekly phone calls (maximum of 5 min) during the treatment period in order to resolve any difficulties or doubts, or to remind them of the importance of reviewing the treatment contents. Participants in both treatment conditions had equal access to the protocol for a maximum period of 18 weeks.

Table 5-1. Main sections of the web platform

Section	Function
"Home"	It is the starting point from which the participant can access the other sections
"Calendar"	It allows the participant to know about pending or achieved tasks as well as the current point in the program
"Review"	It allows the participant to review the treatment modules already completed
"How am I"	It allows participants to monitor their progress through a set of graphs. It also provides feedback about the evolution during the program with regard to their emotional distress and their positive and negative affectivity

Outcome measures

The assessment protocol was included at the beginning of the online program. Participants were assessed at baseline and post-treatment. A detailed description of the measures, the aim of each of them, and the time of assessment can be found in the study protocol (Díaz-García et al., 2017). Measures included in this study were the following:

Diagnostic interview

Mini International Neuropsychiatric Interview Version 5.0.0 (MINI) (Sheehan et al., 1998). The MINI is a short, structured, diagnostic psychiatric interview for DSM-IV and ICD-10 diagnoses. This interview has excellent inter-rater reliability ($k = .88-1.00$) and adequate concurrent validity with the Composite International Diagnostic Interview (Lecrubier et al., 1997).

Primary outcomes

Beck Depression Inventory (BDI-II) (Beck, Steer, & Brown, 1996). It is a widely-used 21-item measure for the evaluation of depression severity, covering all the different symptoms of major depression disorder. The instrument has shown good internal consistency ($\alpha = 0.76$ to 0.95). Cronbach's alpha in the present study was excellent ($\alpha=0.91$)

Beck Anxiety Inventory (BAI) (Beck & Steer, 1993). The BAI is a 21-item symptom checklist designed to assess anxiety symptoms. The internal consistency of the BAI has been found to range from $.85$ to $.94$. Cronbach's alpha in the present study was excellent ($\alpha=0.92$).

Positive and Negative Affect Scale (PANAS) (Watson, Clark, & Tellegen, 1988). This scale evaluates two independent dimensions: PA and NA. The scale showed excellent internal consistency (α between .84 and .90) and convergent and discriminant validity. Cronbach's alpha in the present study was excellent for PANAS+ ($\alpha=0.91$) and good for PANAS- ($\alpha=0.89$).

Secondary outcomes

Diagnosis-specific measures

PD/AG: Self-Reported Panic Disorder Severity Scale (PDSS-SR) (Houck, Spiegel, Shear, & Rucci, 2002). The PDSS-SR is a 7-item self-report measure of panic disorder severity, assessing panic attack frequency, distress during panic attacks, severity of anticipatory anxiety, fear and avoidance of agoraphobic situations, fear and avoidance of physical sensations, and work and social impairment. Cronbach's alpha in the present study was excellent ($\alpha=0.91$)

GAD: Penn State Worry Questionnaire (PSWQ) (Meyer, Miller, Metzger, & Borkovec, 1990). It is a 16-item self-report questionnaire about general anxiety or worry, with good internal consistency, ranging from .91 to .95, and good validity and test-retest reliability. Cronbach's alpha in the present study was good ($\alpha=0.85$).

SAD: Social Interaction Anxiety Scale (SIAS) (Mattick & Clarke, 1998). The SIAS is a 20-item self-report measure that assesses cognitive, affective, and behavioral reactions in interactive social situations. The SIAS has high internal consistency ($\alpha = .88$ to .94) and good test-retest and discriminant reliability, as well as adequate construct validity. Cronbach's alpha in the present study was good ($\alpha=0.88$).

OCD: Obsessive-Compulsive Inventory-Revised (OCI-R) (Foa et al., 2002). The OCI-R is an 18-item scale to assess obsessive-compulsive symptoms. It has good internal consistency ($\alpha = .81$ to .93), good to excellent test-retest reliability ($\alpha = .57$ to .91), good convergent validity, and a solid factor structure.

Personality measures

NEO-five factor Inventory (NEO FFI) (Costa & McCrae, 1992). It is a short version of the NEO-PI-R, designed to assess the five personality dimensions through 60 items. Only the subscales of neuroticism and extraversion are used in

this study. Cronbach's alpha in the present study was good for both NEO FFI_Neuroticism ($\alpha=0.81$) and NEO FFI_Extraversion ($\alpha=0.84$).

Quality of Life

EuroQol 5D (EQ-5D-Spanish version) (Badia, Roset, Montserrat, Herdman, & Segura, 1999). It is a generic measure to assess health-related quality of life that can be used in relatively healthy individuals as well as in groups of patients with different pathologies. Cronbach's alpha in the present study was questionable ($\alpha=0.67$).

Expectation and opinion of treatment scale.

The Expectation of Treatment Scale and Opinion of Treatment Scale, adapted from Borkovec and Nau (Borkovec & Nau, 1972). These scales cover, before and after treatment, how logical the treatment seemed, to what extent it satisfied the patient, whether it could be used to treat other psychological problems, and its usefulness for the patient's specific problem.

Statistical methods

Intention-to-treat analyses and per protocol analyses were performed, and CONSORT recommendations were followed (Schulz et al., 2010). Group differences in participants' socio-demographic and clinical data at baseline were examined in order to confirm that they were comparable after randomization. One-way ANOVAs for continuous variables and Chi-squared tests of independence for categorical variables were used. Intention-to-treat (ITT) using mixed-models with full information maximum likelihood estimation and without any ad hoc imputations were conducted to handle missing data due to participant drop-out (Chakraborty, 2009). This approach uses all the available data, it does not involve any substitution of missing values with supposed or estimated values, and it does not assume that the last measurement is stable (the last observation carried forward assumption) (Hesser, 2015). Mixed model analyses are appropriate for RCTs with multiple time points and pre-to post-only designs with substantial dropout rates (Salim, Mackinnon, Christensen, & Griffiths, 2008). This method has been recommended due to its flexibility in repeated-measures ANOVAs in handling missing data more appropriately (Gueorguieva et al., 2004). The assumption that data were missing completely at random (MCAR) was evaluated using Little's MCAR test. A linear mixed-model for each outcome measure was implemented using the MIXED procedure with one random intercept per subject. An identity covariance structure was specified to model the

covariance structure of the random intercept. For each outcome, *time* was treated as within-group factor and *condition* as a between-group factor. Significant effects were followed up with pairwise comparisons. To complement the results of the ANOVAs and post hoc comparisons, effect sizes were calculated by using the standardized mean difference proposed by Cohen (Cohen, 1988). These effect sizes were calculated to assess both within- and between-group changes, all of them based on a pooled standard deviation. Per protocol analyses (completers only analysis) were also conducted to help to draw conclusions about the maximum treatment efficacy in patients who complied fully with the treatment (Wright & Sim, 2003).

To determine the existence of a clinically significant change in a patient, Jacobson and Truax's method was used (Jacobson & Truax, 1991). This method involves, first, establishing a cut-off score that the patient must achieve in order to move from a dysfunctional to a functional distribution: $C = \frac{S_x M_y + S_y M_x}{S_x + S_y}$; with S_x and S_y being the standard deviation of normal and clinical populations, respectively, and M_y and M_x being the mean deviation of normal and clinical populations, respectively. To obtain these cut-off points, the normative data offered by the Spanish version of each instrument were considered. Second, the method implies estimating whether the change indicated by the scores of the instruments is not due to its measurement error, but instead reflects a reliable, real change in the patient's symptomatology. In this vein, these authors proposed the reliable change index (RCI). $RCI = [(X_{post} - X_{pre}) / S_{diff}]$, where S_{diff} is the standard error of difference: $S_{diff} = \sqrt{2(S_x \sqrt{(1 - r_{xx})})^2}$; with S_x being the standard deviation in the clinical sample and r_{xx} being the reliability of the measure. It was considered statistically significant whether $RCI \geq 1.96$ or $RCI \leq -1.96$ (z-value corresponding to the point on a normal curve of 95% confidence levels). This algorithm indicates that a significant change occurs when $X_{post} - X_{pre} \geq 1.96 * S_{diff}$ or $X_{post} - X_{pre} \leq -1.96 * S_{diff}$. The RCI values for the primary outcomes (BDI-II, BAI, PANAS-P, and PANAS-N) were calculated for the completer sample (participants who provided data at post-treatment). Chi-square tests were performed to evaluate group differences in RCI rates for completers. All statistical analyses were conducted using IBM SPSS Statistics for Windows, version 22.

Results

Participant flow and attrition

Out of the 573 people who expressed initial interest in the study, as the flow diagram shows (Figure 5-1), only 402 performed the initial interview. At this stage, 186 participants failed to meet the inclusion criteria. Finally, 216 were included in the study, and they were randomly allocated to each experimental condition: TIBP, $n=71$; TIBP + PA, $n=73$; WL, $n=72$. Regarding pretreatment assessments, 71 participants performed it in the TIBP, 73 participants in the TIBP + PA, and 72 participants in the WL. A similar number of participants performed the post treatment assessment from both intervention conditions (TIBP, $n=45$; TIBP + PA, $n=46$). No significant differences between the three conditions were found in dropout rates ($X^2 [2] = 3.817, P = .148$). In the TIBP condition, of those who started the program ($n=71$), 26 participants (37%) withdrew from the treatment. In the TIBP + PA condition, a similar pattern was found; of those who started the program ($n=73$), 27 participants (37%) withdrew from the treatment. Finally, in the WL control group, data from 55 participants were obtained after they had spent 16 weeks on the waiting list (76% retention; 24% dropout). Overall, of the 216 participants who started the study, 70 participants withdrew from the program (32%). Data were missing completely at random (MCAR) ($p > .05$).

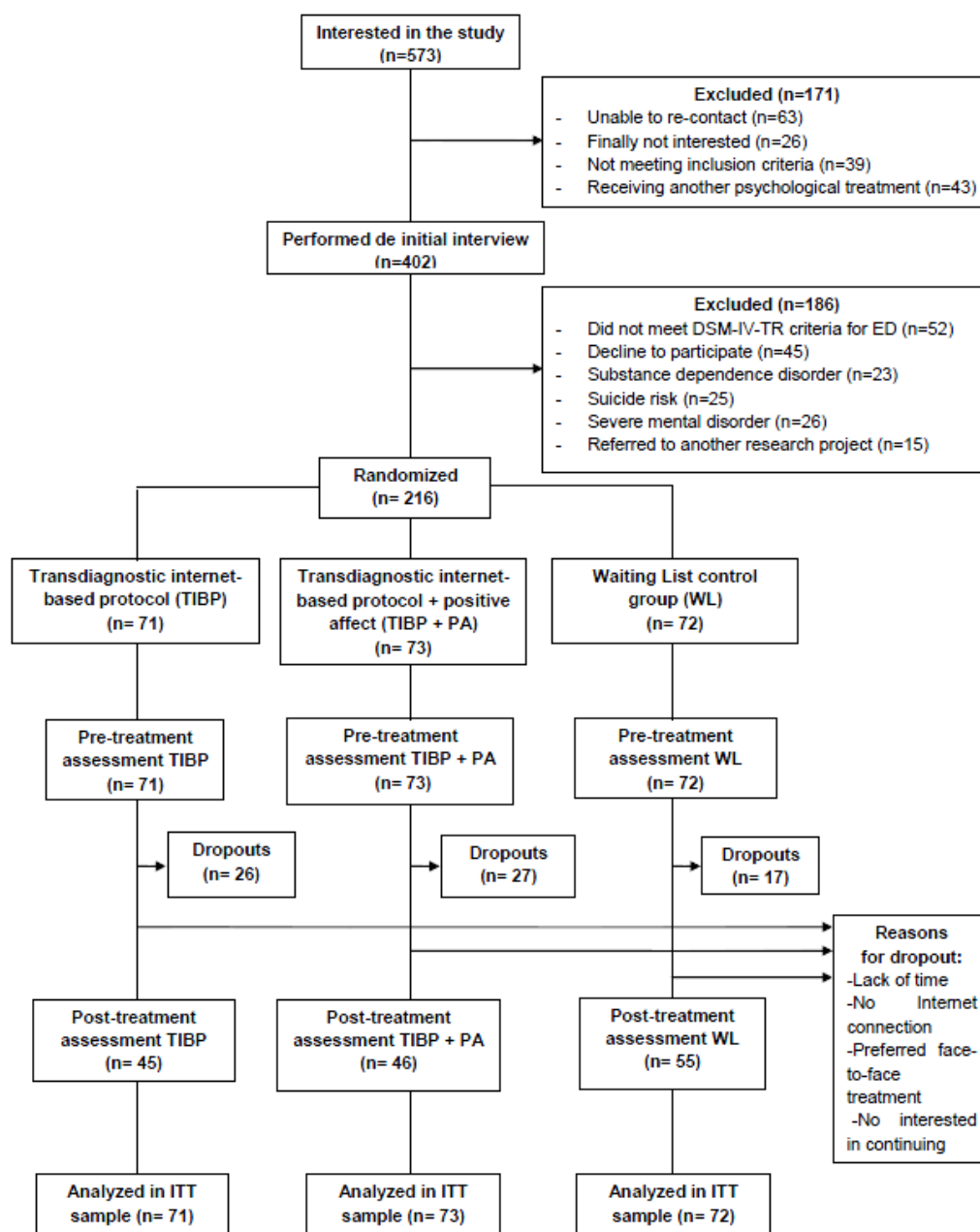


Figure 5-1. Flowchart of participants

Baseline data and participant characteristic

Details about participants' sociodemographic characteristics for each group at pretreatment are presented in Table 5-2. The results indicated that there were no significant differences between the experimental groups before treatment in age ($F_{(2,213)}=2.382$; $P=.095$), gender ($X^2 [2] =0.252$, $P=.882$), marital status ($X^2 [4] =0.547$, $P=.969$), education level ($X^2 [4] =3.655$, $P=.455$), principal diagnostic ($X^2 [18] =15.910$, $P=.59$), or number of comorbid diagnoses ($X^2 [6] =8.781$, $P=.186$), indicating that the randomization was successful. Overall,

participants' mean age was 33.57 years (SD 11.24, range 18-72), the majority were females (72%, 155/216 overall), and most of them were single (58%, 127/216) and had higher studies (76%, 163/216). Principal and comorbid diagnoses are also presented in Table 5-2. Most of participants suffered from GAD (33%, 71/216), followed by SAD (25%, 54/216) and MDD (17%, 36/216). Regarding the patterns of comorbidity in the sample, 42% of the participants (90/216) had at least one comorbid diagnosis, with MDD being the most common comorbid disorder (n=57), followed by GAD (n=11), SAD (n=10), AG (n=7), DD (n=6), and PD (n=1).

Table 5-2. Demographic characteristics of participants at Pre-Assessment

Variable	TIBP (n=71)	TIBP + PA (n=73)	WL (n=72)	Total (n=216)	Statistic	P value
Age (years)					$F(2,213) = 2.382$.095
Mean (SD)	35.82 (13.04)	33.11 (9.74)	31.82 (10.50)	33.57 (11.24)		
Range	18-72	19-52	19-58	18-72		
Gender, n (%)					$X^2(2) = 0.252$.882
Male	20 (28)	22 (30)	19 (26)	61 (28)		
Female	51 (72)	51 (70)	53 (74)	155 (72)		
Marital Status, n (%)					$X^2(4) = 0.547$.969
Single	44 (62)	41 (56)	42 (58)	127 (58)		
Married/Partnered	23 (32)	27 (37)	25 (35)	75 (35)		
Divorced	4 (6)	5 (7)	5 (7)	14 (7)		
Education Level, n (%)					$X^2(4) = 3.655$.455
Basic studies	1 (1)	5 (7)	3 (4)	9 (4)		
Medium studies	15 (21)	12 (16)	17 (24)	44 (20)		
Higher studies	55 (78)	56 (77)	52 (72)	163 (76)		
Principal diagnosis, n (%)					$X^2(18) = 15.910$.599
MDD	11 (15)	9 (12)	16 (22)	36 (17)		
DD	1 (1)	0 (0)	2 (3)	3 (1)		
GAD	26 (37)	21 (29)	24 (33)	71 (33)		
PD/AG	4 (6)	6 (8)	6 (8)	16 (7)		
PD	2 (3)	4 (6)	3 (4)	9 (4)		
AG	6 (9)	6 (8)	1 (1)	13 (6)		
SAD	15 (21)	23 (32)	16 (22)	54 (25)		
OCD	3 (4)	1 (1)	2 (3)	6 (3)		
ADNOS	3 (4)	3 (4)	1 (1)	7 (3)		
MDNOS	0 (0)	0 (0)	1 (1)	1 (1)		
Number of comorbid diagnoses, n (%)					$X^2(6) = 8.781$.186
None	32 (45)	19 (26)	34 (47)	85 (39)		
1	28 (39)	36 (49)	26 (36)	90 (42)		
MDD	18	22	15	57		

	DD	1	2	3	6
	GAD	2	7	2	11
	PD/AG	0	0	0	0
	PD	0	0	1	1
	AG	3	2	2	7
	SAD	4	3	3	10
	OCD	0	0	0	0
	ADNOS	0	0	0	0
	MDNOS	0	0	0	0
2		7 (10)	12 (16)	7 (10)	26 (12)
	MDD & GAD	2	3	2	7
	MDD & PD/AG	1	1	1	3
	MDD & PD	1	1	2	4
	MDD & AG	0	2	0	3
	MDD & OCD	1	0	0	1
	DD & SAD	0	1	0	1
	GAD & SAD	2	1	1	4
	GAD & AG	0	2	0	2
	PD/AG & SAD	0	0	1	1
	SAD & OCD	0	1	0	1
3		4 (6)	6 (8)	5 (7)	15 (7)
	MDD & GAD & AG	1	1	2	4
	MDD & GAD & SAD	0	2	2	4
	MDD & GAD & OCD	0	1	0	2
	MDD & PD & SAD	0	2	0	2
	MDD & PD & OCD	0	0	1	1
	MDD & AG & SAD	1	0	0	1
	MDD & SAD & OCD	1	0	0	1
	GAD & PD/AG & SAD	1	0	0	1

Note. SD, standard deviation; TIBP, Transdiagnostic Internet-Based Protocol; TIBP + PA, Transdiagnostic Internet-Based Protocol + Positive Affect Component; WL, Waiting List; MDD, Major Depressive Disorder; DD, Dysthymic Disorder; GAD, Generalized Anxiety Disorder; PD, Panic Disorder; AG, Agoraphobia; SAD, Social Anxiety Disorder; OCD, Obsessive-Compulsive Disorder; ADNOS, Anxiety Disorder Not Otherwise Specified; MDNOS, Mood Disorder Not Otherwise Specified.

Regarding the clinical characteristics of the participants in each experimental condition at pretreatment (see **¡Error! La autoreferencia al marcador no es válida.**), no statistically significant differences were found between groups on any of the primary and secondary outcomes.

Table 5-3. Clinical characteristics of participants at Pre-Assessment

Measure	TIBP (n=71)	TIBP + PA (n=73)	WL (n=72)	Total (n=216)	Statistic	P value
Primary outcomes (M, SD)						
BDI-II	25.35 (11.33)	29.07 (11.33)	26.31 (12.43)	26.93 (11.76)	F (2,213) = 1.966	0.143
BAI	21.14 (12.10)	23.58 (11.50)	21.87 (12.56)	22.23 (12.04)	F (2,197) = 0.719	0.489
PANAS						
- Positive	20.72 (6.52)	19.32 (6.22)	19.28 (5.67)	19.84 (6.22)	F (2,213) = 1.277	0.281
- Negative	30.68 (7.73)	31.96 (8.79)	28.63 (9.03)	30.43 (8.61)	F (2,213) = 2.807	0.063
Secondary outcomes (M, SD)						
Personality measures						
NEO FFI_Neuroticism	31.54 (6.65)	34.11 (8.18)	31.39 (8.20)	32.36 (7.78)	F (2,213) = 2.853	0.060
NEO FFI_Extraversion	21.49 (8.77)	19.26 (7.59)	21.79 (8.66)	20.84 (8.39)	F (2,213) = 1.991	0.139
EQ-5D	54.60 (17.76)	54.78 (19.75)	51.91 (17.81)	53.75 (18.44)	F (2,197) = 0.511	0.601

Note. M, mean; SD, standard deviation; TIBP, Transdiagnostic Internet-Based Protocol; TIBP + PA, Transdiagnostic Internet-Based Protocol + Positive Affect Component; WL, Waiting List; BDI-II, Beck Depression Inventory-II; BAI, Beck Anxiety Inventory; PANAS, Positive and Negative Affect Scale; NEO FFI, NEO-Five Factor Inventory; EQ-5D, EuroQoL-5D questionnaire. Unfortunately, 16 participants did not complete the BAI and EQ-5D measures at pretreatment due to technical problems in the online assessment. Therefore, the number of participants in these measures was as follows: 63 for TIBP, 69 for TIBP + PA, and 68 for WL.

Finally, regarding diagnosis-specific measures, no statistically significant differences were found between groups on any sociodemographic or clinical

variables, with the exception of PDSS. In relation to this variable, significant differences between groups were found for the number of comorbid diagnoses ($X^2(6) = 14.30$; $p = .026$).

Effectiveness of the intervention on primary and secondary outcomes at pre-post

Primary outcomes

Finally, quality of life measures (EUROQOL) showed a significant time effect ($F(1,152.98) = 32.98$, $P < 0.001$) and significant interaction effects ($F(2,152.73) = 9.28$, $P < 0.001$). Both intervention groups experienced significant improvements in quality of life at post-treatment, and this improvement was not found in the waiting list control group. Within-group comparisons indicated moderate effect sizes in the TIBP condition ($d = 0.53$), moderate effect sizes in the TIBP + PA condition ($d = 0.70$), and non-significant changes in the WL control group. Between-group comparisons revealed that participants who received the treatment (with or without the specific component to up-regulate PA) scored higher on quality of life at post-treatment, compared to the WL, with moderate effect sizes in the TIBP condition ($d = 0.60$) and large effect sizes in the TIBP + PA condition ($d = 0.86$) (see **¡Error! La autoreferencia al marcador no es válida.** for details). The differences between the two treatment groups were not statistically significant.

Table 5-4 includes the means, SDs, within-group and between-group effect sizes, and confidence intervals for all the primary outcome measures in the three experimental groups, based on the intention-to-treat sample.

The analysis revealed a significant time effect on all primary measures: BDI-II ($F(1,161.07) = 163.47, p < 0.001$); BAI ($F(1,141.80) = 73.84, p < 0.001$), PANAS+ ($F(1,180.13) = 59.48, p < 0.001$) and PANAS- ($F(1,355) = 194.21, p < 0.001$). In addition, there were significant interaction effects for BDI-II ($F(2,160.94) = 44.68, p < 0.001$), BAI ($F(2,141.64) = 18.76, p < 0.001$), PANAS+ ($F(2,179.94) = 16.76, p < 0.001$) and PANAS- ($F(2,355) = 51.58, p < 0.001$). For this latter variable (PANAS-), an ANCOVA was performed to control for differences found among the three conditions at pretreatment. Post hoc tests indicated that both intervention groups experienced significant improvements in all variables. This improvement was not found in the waiting list control group.

For the three primary outcomes, within-group comparisons indicated significant pre-post reductions in the two experimental conditions, with large effect sizes for the BDI-II ($d = 1.19$) and PANAS- ($d = 1.28$), and moderate effect sizes for the BAI ($d = 0.63$) and PANAS+ ($d = 0.69$) in the TIBP condition. In the TIBP + PA condition, effect sizes were large on all the primary outcomes ($d = 1.42$, BDI-II; $d = 0.91$, BAI; $d = 1.27$, PANAS+; $d = 1.26$, PANAS-). Between-group comparisons revealed that participants who received the treatment (with and without the specific component to up-regulate positive affect) scored better at post-treatment, compared to the WL group. Greater reductions were found in the BDI-II scores in the TIBP condition, compared to the WL condition (mean difference $-13.61, p < 0.001$; $d = 1.18, 95\%CI: -1.61$ to -0.76), as well as between the TIBP + PA condition and WL (mean difference $-14.31, p < 0.001$; $d = 1.05, 95\%CI: -1.46$ to -0.63), with large effect sizes. No differences were found between the two experimental conditions (TIBP and TIBP + PA) (mean difference $0.70, p = 0.76, d = 0.10, 95\%CI: -0.51$ to 0.31). The results for BAI scores were similar to the pattern of findings for the BDI: greater reductions in the TIBP condition (mean difference $-8.19, p = 0.001$; $d = 0.63, 95\%CI: -1.07$ to -0.20) and TIBP + PA condition (mean difference $-9.28, p < 0.001$; $d = 0.68, 95\%CI: -1.10$ to -0.26), compared to WL, with medium effect sizes, and no differences between the two experimental conditions (mean difference $1.09, p = 0.65; d = 0.05, 95\%CI: -0.39$ to 0.49). Finally, patients in the TIBP condition experienced a higher increase in PA (PANAS+), compared to WL (mean difference $5.42, p < 0.001; d$

= 0.74, 95%CI: 0.33 to 1.15), with moderate effect sizes, and greater reductions in NA (PANAS-) (mean difference -8.34, $p < 0.001$; $d = 0.99$, 95%CI:-1.41 to -0.57) compared to WL, with large effect sizes. Participants in the TIBP + PA condition experienced the same pattern as the participants in the TIBP condition, but achieving large effect sizes for both higher PA (mean difference 7.86, $p < 0.001$; $d = 0.90$, 95%CI: 0.49 to 1.31) and lower NA (-8.32, $p < 0.001$; $d = 0.91$, 95%CI:-1.32 to -0.50) than participants in the WL condition. No differences were found between the two experimental conditions on PA (mean difference -2.44, $p=0.077$; $d = 0.25$, 95%CI:-0.66-0.17) or NA (mean difference -0.02 $p=0.99$; $d = 0.01$, 95%CI:-0.42 to 0.40).

Secondary outcomes

Finally, quality of life measures (EUROQOL) showed a significant time effect ($F(1,152.98) = 32.98$, $P < 0.001$) and significant interaction effects ($F(2,152.73) = 9.28$, $P < 0.001$). Both intervention groups experienced significant improvements in quality of life at post-treatment, and this improvement was not found in the waiting list control group. Within-group comparisons indicated moderate effect sizes in the TIBP condition ($d = 0.53$), moderate effect sizes in the TIBP + PA condition ($d = 0.70$), and non-significant changes in the WL control group. Between-group comparisons revealed that participants who received the treatment (with or without the specific component to up-regulate PA) scored higher on quality of life at post-treatment, compared to the WL, with moderate effect sizes in the TIBP condition ($d = 0.60$) and large effect sizes in the TIBP + PA condition ($d = 0.86$) (see **¡Error! La autoreferencia al marcador no es válida.** for details). The differences between the two treatment groups were not statistically significant.

Table 5-4 includes the means, SDs, within-group and between-group effect sizes, and confidence intervals for secondary outcomes related to personality and quality of life measures in the three experimental groups, based on the intention-to-treat sample.

Regarding the personality measures, the analysis revealed a significant time effect on NEO FFI_Neuroticism ($F(1,355) = 62.47, P < 0.001$) and NEO FFI_ Extraversion ($F(1,153.63) = 17.79, P < 0.001$). Furthermore, there were significant interaction effects for both NEO FFI_Neuroticism ($F(2,355) = 29.07, P < 0.001$) and NEO FFI_ Extraversion ($F(2,153.54) = 17.52, P < 0.001$). For NEO FFI_Neuroticism, an ANCOVA was performed to control for differences found among the three conditions at pretreatment. For both subscales of the NEO FFI, within-group comparisons indicated a significant pre-to-post reduction in neuroticism in the two experimental conditions, with moderate effect sizes in NEO FFI_Neuroticism ($d = 0.73, \text{TIBP}$; $d = 0.78, \text{TIBP} + \text{PA}$), and a significant pre-to-post increase in extraversion in the two experimental conditions, with a small effect size in the TIBP condition ($d = 0.30$) and a moderate effect size in the TIBP + PA condition ($d = 0.65$). In the WL control group, significant changes with small effect sizes were also found on NEO FFI_Extraversion ($d = 0.22$). Between group comparisons revealed that participants who received the treatment scored better at post-treatment on NEO FFI_Neuroticism in both intervention groups compared to the WL group, with moderate effect sizes ($d = 0.61, \text{TIBP}$; $d = 0.47, \text{TIBP} + \text{PA}$). NEO FFI_Extraversion showed better scores with small effect sizes in both intervention conditions ($d = 0.46, \text{TIBP}$; $d = 0.48, \text{TIBP} + \text{PA}$), compared to WL. No statistically significant differences were found between the two experimental conditions on the personality measures.

Finally, quality of life measures (EUROQOL) showed a significant time effect ($F(1,152.98) = 32.98, P < 0.001$) and significant interaction effects ($F(2,152.73) = 9.28, P < 0.001$). Both intervention groups experienced significant improvements in quality of life at post-treatment, and this improvement was not found in the waiting list control group. Within-group comparisons indicated moderate effect sizes in the TIBP condition ($d = 0.53$), moderate effect sizes in the TIBP + PA condition ($d = 0.70$), and non-significant changes in the WL control group. Between-group comparisons revealed that participants who received the treatment (with or without the specific component to up-regulate PA) scored higher on quality of life at post-treatment, compared to the WL, with

moderate effect sizes in the TIBP condition ($d = 0.60$) and large effect sizes in the TIBP + PA condition ($d = 0.86$) (see **¡Error! La aut Referencia al marcador no es válida.** for details). The differences between the two treatment groups were not statistically significant.

Table 5-4. Means, standard deviations, within-group and between-group effect sizes for primary outcomes, personality measures, and quality of life measures at pre and post-treatment, based on intention-to-treat sample (N=216)

		Mean (SD)		Within-group effect size, <i>d</i> [95% CI]	Between-group effect size, <i>d</i> [95% CI]
		Pre-treatment	Post-treatment		
Primary Outcomes					
BDI-II	TIBP	25.35 (11.33)	11.76 (9.02)	1.19 [0.90; 1.48]	TIBP vs TIBP+PA -0.10 [-0.51; 0.31]
	TIBP + PA	29.07 (11.33)	12.78 (10.76)	1.42 [1.09; 1.76]	TIBP vs WL -1.18 [-1.61; -0.76]
	WL	26.31 (12.42)	26.09 (13.99)	0.02 [-0.13; 0.16]	TIBP+PA vs WL -1.05 [-1.46; -0.63]
BAI	TIBP	21.14 (12.10)	13.46 (10.26)	0.63 [0.38; 0.87]	TIBP vs TIBP+PA 0.05 [-0.39; 0.49]
	TIBP + PA	23.58 (11.50)	12.97 (10.33)	0.91 [0.64; 1.18]	TIBP vs WL -0.63 [-1.07; -0.20]
	WL	21.87 (12.56)	21.67 (14.41)	0.02 [-0.12; 0.15]	TIBP+PA vs WL -0.68 [-1.10; -0.26]
PANAS +	TIBP	20.72 (6.52)	25.24 (7.10)	-0.69 [-0.92; -0.45]	TIBP vs TIBP+PA -0.25 [-0.66; 0.17]
	TIBP + PA	19.32 (6.22)	27.28 (9.21)	-1.27 [-1.58; -0.95]	TIBP vs WL 0.74 [0.33; 1.15]
	WL	19.28 (5.68)	19.86 (7.27)	-0.01 [-0.22; 0.20]	TIBP+PA vs WL 0.90 [0.49; 1.31]
PA NAS-	TIBP	30.68 (7.73)	20.71 (6.81)	1.28 [0.96; 1.60]	TIBP vs TIBP+PA -0.01 [-0.42; 0.40]
	TIBP + PA	31.96 (8.79)	20.78 (8.37)	1.26 [0.94; 1.57]	TIBP vs WL -0.99[-1.41; -0.57]
	WL	28.63 (9.03)	28.76 (8.99)	-0.04[-0.22; 0.14]	TIBP+PA vs WL -0.91[-1.32; -0.50]

Secondary Outcomes***Personality measures***

NEOFFI_Neuroticism	TIBP	31.54 (6.65)	26.64 (7.83)	0.73 [0.50; 0.96]	TIBP vs TIBP+PA	-0.12 [-0.54; 0.29]
	TIBP + PA	34.11 (8.18)	27.67 (8.37)	0.78 [0.51; 1.05]	TIBP vs WL	0.61 [-1.01; -0.21]
	WL	31.39 (8.20)	31.71 (8.56)	0.04 [-0.22; 0.20]	TIBP+PA vs WL	-0.47 [-0.87; -0.08]
NEOFFI_Extraversion	TIBP	21.49 (8.77)	24.13 (8.41)	0.30 [-0.45; -0.14]	TIBP vs TIBP+PA	-0.01 [-0.42; 0.40]
	TIBP + PA	19.26 (7.59)	24.22 (7.64)	0.65 [-0.88; -0.42]	TIBP vs WL	0.46 [0.06; 0.86]
	WL	21.79 (8.66)	19.84 (10.02)	0.22 [0.07; 0.37]	TIBP+PA vs WL	0.48 [0.08; 0.88]
<i>Quality of Life</i>						
EUROQOL	TIBP	54.60 (17.76)	64.05 (18.78)	0.53 [-0.80; -0.25]	TIBP vs TIBP+PA	-0.25 [-0.70; 0.19]
	TIBP + PA	54.78 (19.75)	68.81 (18.37)	0.70 [-0.97; -0.43]	TIBP vs WL	0.60 [0.17; 1.04]
	WL	51.91 (17.81)	52.55 (18.96)	0.04 [-0.21; 0.14]	TIBP+PA vs WL	0.86 [0.44; 1.29]

Subgroup analysis

To assess the differences in diagnosis-specific measures, subgroup analyses were conducted. The results revealed a significant interaction effect for the PSWQ ($F(2,42) = 10.71, P < 0.001$) and SIAS ($F(2,39) = 8.97, P = 0.001$). For the PDSS variable, an ANCOVA was performed to control for differences found among the three experimental groups in the number of comorbid diagnoses at pretreatment. Covariate analysis indicated that the groups did not differ significantly at post-treatment (PDSS; $F(2,23) = 3.36, P = 0.053$). These analyses were not conducted for OCD due to the small number of participants who met the diagnostic criteria for OCD ($n=4$).

Expectations and satisfaction

Table 5-5 lists the results for the two interventions groups. Before the treatment, all the scores were high. The analysis revealed statistically significant differences between the two conditions on expectations about the treatment: before treatment, participants in the TIBP + PA condition considered the treatment more “logical” ($F(1,89) = 4.49, P = 0.037$), more “satisfactory” ($F(1,89) = 6.29, P = 0.014$), more “recommendable to others” ($F(1,89) = 6.15, P = 0.015$), and “more useful for other psychological problems” ($F(1,89) = 7.38, P = 0.008$) than the TIBP participants did. In addition, at post-treatment, participants’ satisfaction scores were also high. The analysis revealed statistically significant differences between the two conditions on satisfaction: after treatment, participants in the TIBP + PA condition considered the treatment more “satisfactory” ($F(1,89) = 4.10, P = 0.046$), “recommendable to others” ($F(1,89) = 6.79, P = 0.011$), “more useful for other psychological problems” ($F(1,89) = 5.13, P = 0.026$), and “more useful for the patient” ($F(1,89) = 5.91, P = 0.017$) than participants in the TIBP condition did.

Table 5-5. Means and standard deviations for expectations and satisfaction

Statements	Expectations N; M (SD)	Satisfaction N; M (SD)
How logical do you think this treatment is?		
Total sample	91; 8.21 (1.55)	91; 8.21 (1.67)
TIBP	45; 7.87 (1.71)	45; 8.07 (1.68)
TIBP + PA	46; 8.54 (1.31)	46; 8.35 (1.66)
How satisfied are you with the treatment received?		
Total sample	91; 8.21 (1.75)	91; 7.63 (2.02)
TIBP	45; 7.76 (1.86)	45; 7.20 (2.04)
TIBP + PA	46; 8.65 (1.54)	46; 8.04 (1.93)
To what extent do you feel confident about recommending this treatment to a friend who has the same problems?		
Total sample	91; 8.36 (1.77)	91; 8.01 (2.12)
TIBP	45; 7.91 (1.95)	45; 7.44 (2.32)
TIBP + PA	46; 8.80 (1.45)	46; 8.57 (1.75)
Do you think this treatment could be useful for treating other psychological disorders?		
Total sample	91; 8.03 (1.72)	91; 7.88 (1.76)
TIBP	45; 7.56 (1.79)	45; 7.47 (1.89)
TIBP + PA	46; 8.50 (1.52)	46; 8.28 (1.53)
To what extent do you think the treatment was helpful to you?		
Total sample	91; 7.44 (1.93)	91; 7.30 (2.07)
TIBP	45; 7.13 (1.87)	45; 6.78 (2.00)
TIBP + PA	46; 7.74 (1.97)	46; 7.80 (2.03)

Note. M= Mean; SD= Standard Deviation; TIBP= *Transdiagnostic Internet-based protocol*; TIBP + PA *Transdiagnostic Internet-based protocol + positive affect component*. Scale ranging from 0 to 10, with higher scores indicating greater satisfaction.

Clinically meaningful improvement: Reliable change

Based on the two criteria proposed by Jacobson and Truax to estimate clinically meaningful improvement, patients were classified as *recovered* if their score on an instrument was a change that exceeded the 1.96 RCI value and if that score exceeded the C cut-off, *improved* if the score was a change that exceeded the 1.96 RCI value, but did not exceed the C cut-off, *stable* if the score did not exceed either of the two criteria, and *deteriorated* if the score was a change that exceeded the 1.96 RCI value, but in the direction of worsening.

The clinical change has been expressed graphically to facilitate a more intuitive interpretation (see Figure 5-2). At post-treatment, statistically significant differences were found between the three conditions in these percentages on all the primary outcomes: BDI-II ($X^2(6) = 51.46$; $p < .01$), BAI ($X^2(6) = 27.78$; $p < .01$), PANAS-P ($X^2(6) = 22.98$; $p = 0.001$), and PANAS-N ($X^2(6) = 34.97$; $p < .01$). Out of 45 completers in the TIBP condition, 22 (48.89%) showed reliable recovery on the BDI-II, 11 (29.73%) showed reliable recovery on the BAI, 10 (22.22%) showed reliable recovery on the PANAS-P, and 20 (44.44%) showed reliable recovery on the PANAS-N. In this group, only 1 participant had reliable deterioration on the BDI-II (2.22%), 1 had deterioration on the BAI (2.70%), 2 had reliable deterioration on the PANAS-P (4.44%), and no participant had reliable deterioration on the PANAS-N. Out of 46 completers in the TIBP + PA condition, 28 (60.87%) showed reliable recovery on the BDI-II, 15 (35.71%) showed reliable recovery on the BAI, 16 (34.78%) showed reliable recovery on the PANAS-P, and 18 (39.13%) showed reliable recovery on the PANAS-N. In this group, only 1 participant had reliable deterioration on the BAI (2.38%), and 1 participant had deterioration on the PANAS-P (2.17%). Finally, for the WL group, participants showed high percentages of reliable deterioration on all the primary outcomes in comparison with the intervention groups. Overall, participants who received the transdiagnostic Internet-based interventions (TIBP or TIBP + PA) showed a higher percentage of recovery compared to WL.

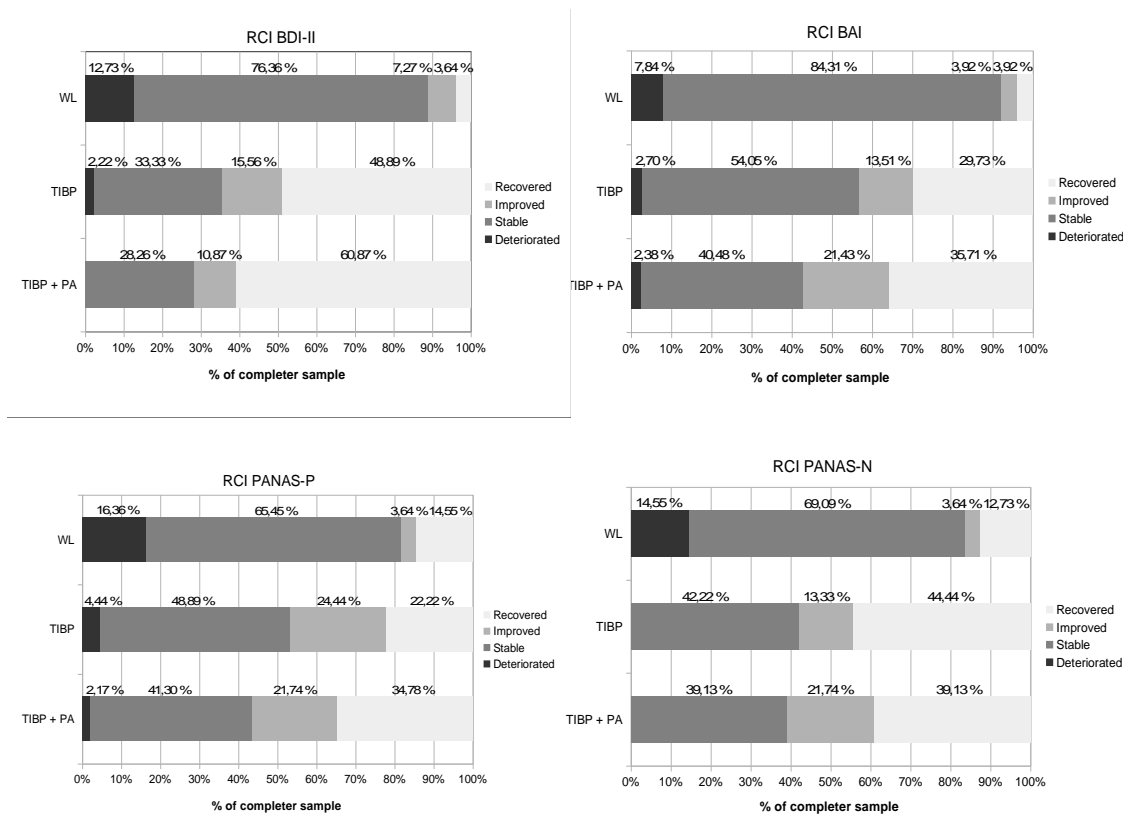


Figure 5-2. Proportion of completers in each of the three conditions that showed: reliable recovery, reliable improvement, no reliable change (stable), and reliable deterioration on the BDI-II, BAI, PANAS-P and PANAS-N at post-treatment according to reliable change index calculations

Discussion

The main objective of this study was to test the efficacy of a transdiagnostic Internet-based psychological treatment protocol, with and without a specific component to up-regulate positive affect, versus a waiting list control group, for individuals from a community sample with one or more ED diagnosis.

The results showed that, on the primary outcome measures (BDI-II, BAI, and PANAS), there was a significant time effect, corresponding to medium (BAI and PANAS-P) and large effect sizes (BDI-II and PANAS-N) in the TIBP condition, and large effect sizes for all measures in the TIBP + PA condition. In the WL group, the effect size was minimal. These results are comparable with those reported in other transdiagnostic trials in which effect sizes are larger for depression than for anxiety, and higher for the PANAS-P than for the PANAS-N (Farchione et al., 2012a). The interaction effect showed that the online transdiagnostic treatment was effective in treating ED, compared to the WL, with medium between-group effect sizes for the BAI and PANAS-P, and large effect

sizes for the BDI-II and PANAS-N in the TIBP condition. In the TIBP + PA condition, large between-group effect sizes for all primary measures were found when compared to the WL control group, with the exception of BAI, which obtained medium effect sizes. As predicted, both self-applied protocol modalities (TIBP and TIBP + PA) led to significantly greater reductions (relative to the waiting-list control group) in depressive and anxious symptomatology, as well as significant decreases in NA and increases in PA measures.

On the secondary outcomes of personality and quality of life measures (NEOFFI and EQ-5D), the analysis also revealed a significant change from pre to post treatment. The effect sizes were medium in both intervention groups on all these variables (with the exception of NEOFFI_Extraversion, which was smaller in the TIBP condition). In the WL group, small effect sizes were also found for the NEOFFI_Extraversion variable, but showing that participants in this group experienced significantly lower levels of extraversion after the waiting period. Between-group comparisons revealed that participants who received the treatment (with and without the specific component to up-regulate positive affect) scored better at post-treatment on these measures, compared to the WL group. These findings contribute to the study of the “malleability” of neuroticism proposed by Barlow (2013), who suggests that personality dimensions may be malleable over time. In the present study, some strategies were proposed to modify PA (extraversion) and, although significant effects were found between the two intervention groups and the WL, further research is needed on this topic to explore the effect of this specific component on increasing wellbeing and PA. Regarding the diagnosis-specific measures, results showed a statistically significant change from pre to post treatment, corresponding to large within-group effect sizes in both treatment groups. In addition, large between-group effect sizes at post-treatment were found when comparing both interventions to the WL control group. No effect sizes were obtained for OCD, due to the small number of participants who met the diagnostic criteria for OCD.

A second aim of this study was to assess the effects of the specific treatment component designed to up-regulate PA, with the hypothesis that the TIBP + PA condition would significantly outperform the TIBP condition on the PA measures. Although the results showed small effect sizes between the two interventions on these measures, the effects were non-significant, suggesting that the sample size was underpowered and not large enough to detect differences between the two groups. Although there was no significant additional

benefit of the PA component, effect sizes were consistently larger in this arm, compared to the standard transdiagnostic protocol (TIBP condition). In addition, it is also important to highlight that participants in the TIBP + PA condition showed higher percentages of reliable recovery and lower percentages of reliable deterioration than in the TIBP condition. These results make sense based on the overarching rationale for the inclusion of the specific therapeutic component to directly up-regulate PA. However, future studies will be needed to achieve a deeper understanding of the relationship between treatments that include PA components and changes in PA measures.

Another objective of the study was to test the effectiveness of the Internet-based program developed to apply the treatment protocol over the Internet with minimal support by clinicians. The overall expectations and satisfaction expressed by the participants in the two intervention groups were high, and both protocols were well accepted. However, the analysis revealed that, before and after treatment, participants in the TIBP + PA condition reported feeling more satisfied with the treatment, would recommend it to a friend, and considered the treatment to be more useful for other psychological problems, compared to the participants in the TIBP condition. The higher levels of expectations and satisfaction in the TIBP + PA condition may be due to the number of modules included in this condition (16) in comparison with the modules in the TIBP condition (12), although participants in the intervention groups did not know the number of modules in each intervention. This result may be influenced by the role of expectations before and during an online psychological intervention, which is consistent with the literature showing that treatment expectations became more favorable over time (Meyerhoff & Rohan, 2016). One potentially positive feature that could be added to the satisfaction with the online treatment measure is the therapist support through the weekly phone calls and the ICT-support based on automated emails and feedback from the program. This aspect could be influencing both conditions and should have been assessed in order to draw more definitive conclusions.

Regarding the reliable change indexes, significant improvements were found in the two treatment conditions compared to the WL. Overall, participants who received the transdiagnostic Internet-based interventions (TIBP or TIBP + PA) showed higher recovery percentages and less deterioration compared to WL, with slightly better results for the TIBP + PA condition

Overall, the data revealed that participants receiving the online transdiagnostic treatment demonstrated significant improvements, compared to WL, on all primary and secondary outcomes, with moderate to large effect sizes, which coincides with the results of a recent meta-analysis of transdiagnostic interventions (Newby et al., 2015). These results can also be compared to the results obtained in studies with face-to-face transdiagnostic protocols (Farchione et al., 2012) and other transdiagnostic protocols applied over the Internet, but without components for up-regulating PA (Mcevoy et al., 2009; Titov et al., 2015). In addition, in the present study, the condition with the specific component to up-regulate PA revealed larger treatment effects on measures of positive affectivity and quality of life compared to the WL condition, and the effect sizes were larger than those found in the TIBP condition for the same measures. However, these differences are not found when comparing the two intervention groups on the PA measures. Finally, the online intervention was well accepted, with high scores on both expectations and satisfaction.

This study had several strengths. First, this study raises a novel focus in the field of transdiagnostic treatments. To the best of our knowledge, this is the first study of a transdiagnostic Internet-based treatment for ED with a specific component to up-regulate positive affectivity. Overall, the findings indicate that ED can be effectively treated with a transdiagnostic intervention via the Internet for depressive and anxious symptomatology, as well as for positive and negative affectivity and other temperamental and quality of life measures. Regarding PA measures, promising effects were found, indicating that positive emotions play a fundamental role in the construction of psychological strengths (Algoe & Fredrickson, 2011; Catalino & Fredrickson, 2011) and can be addressed from a transdiagnostic perspective (Carl, Soskin, Kerns, & Barlow, 2013; Carl, Fairholme, Gallagher, Thompson-Hollands, & Barlow, 2014). Furthermore, the PANAS scale was used in this study as a primary outcome to assess PA. Although this scale is one of the most widely and frequently used scales to assess PA and NA, it might be necessary to consider developing another measure that may be more sensitive to changes in PA. Moreover, this study included a large sample of people from a community sample, representing the heterogeneous population suffering from ED but not receiving primary or specialized care, with or without the presence of comorbidity. In this vein, the transdiagnostic protocol represents a successful approach to the treatment of multiple disorders in a parsimonious manner (Barlow et al., 2017). Participants in

the study seemed to be interested in the use of adaptive emotion regulation strategies, whether or not they were related to their own difficulty, which is the basis of transdiagnostic proposals. These interventions emphasize the essential processes underlying different disorders and the use of core “higher-order” strategies that eliminate the need for multiple diagnosis-specific manuals (Mansell, Harvey, Watkins, & Shafran, 2009). Moreover, the Internet-based format of this transdiagnostic protocol facilitates the availability and administration of the program, in order to provide support to anyone in need.

This study also has some limitations that should be mentioned. First, although this study expected dropout rates of around 30%, based on the literature (Andrews et al., 2010; Van Ballegooijen et al., 2014), a higher attrition rate was found at the end of the study. However, this issue deserves special attention. On the one hand, the definition of attrition differs and can be understood as premature termination (Hatchett & Park, 2003), (non-)persistence (Donkin & Glozier, 2012), (non-)adherence, or the extent to which an individual is exposed to the content of an intervention (Christensen, Griffiths, & Farrer, 2009). In the present study, only participants who completed all the treatment modules were considered completers, whereas the rest were treated as drop outs, although in other studies, only participants who completed a percentage of the modules were considered completers (Erickson, 2003; García-Escalera et al., 2018). In addition, adherence to Internet-based interventions is associated with the type of guidance, achieving 28% non-adherence when therapist-guided, and 38% when administrative support is given (Richards & Richardson, 2012). The present study combined human and ICT-support, reaching a 37% dropout rate in the treatment conditions. These results are not far from those found in the existing literature on Internet-based interventions. However, further research on attrition is needed in order to better design Internet-based treatments and increase retention. Second, although small effect sizes were found between the two intervention groups on the PA measures, there was not enough statistical power to detect significant differences between the two conditions. Therefore, future research should use an adequately powered sample to test the differential effects of adding a specific therapeutic component to up-regulate PA. Another limitation of the study is the different number of modules in the two protocols. To control this, equal time was given to all the participants in order to allow them to use the program as much as they liked throughout the whole process. However, future studies should show that the differential effect of the PA component is not

simply due to the larger number of modules in the protocol. In addition, follow-ups were not included in this study due to time limitations, and so long-term effects of this intervention will be presented in further research.

Conclusions

In summary, the results point out the efficacy of a transdiagnostic Internet-based psychological treatment protocol, including a specific component to up-regulate positive affect or not, for individuals from a community sample with a diagnosis of ED. These findings show that this online transdiagnostic treatment improved the clinical situation of participants, providing them with tools and strategies to be able to face problems and difficulties more effectively. Future lines of research should be focus on carrying out dismantling designs in order to determine which are the active components of the protocol and, especially, the contribution of the PA modules as well as analyze the effectiveness of the online treatment in other populations such as primary care centers. Furthermore, the existing techniques and strategies to improve PA should require further study in order to delimit which ones are more effective to be included as a specific component to up-regulate PA in current psychological interventions.

This intervention contribute to improve the efficiency and effectiveness of current treatment programs for ED, promoting the dissemination of EBTs and helping to decrease the high prevalence of ED.

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Chapter 6: Dropping out of a transdiagnostic online intervention: A qualitative analysis of client's experiences

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Dropping out of a transdiagnostic online intervention: A qualitative analysis of client's experiences

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Abstract

Introduction: An important concern in Internet-based treatments (IBT) for emotional disorders is the high dropout rates among these protocols. Although dropout rates are usually reported in research studies, there are very few studies exploring qualitatively the experiences of patients who drop out of IBT. Examining the experiences of these clients may help to find solutions in order to tackle this problem.

Method: A Consensual Qualitative Research was applied with the aim of establishing domains, categories and core ideas associated to the treatment dropout of 10 intentionally selected patients who dropped-out of a transdiagnostic IBT.

Results: 22 categories were identified within 6 domains. Among the clients an undeniable pattern arose regarding the insufficient support due to the absence of a therapist and the lack of specificity of the contents to their own problems.

Conclusions: The analyzed content has direct impact on the clinical application of IBTs. A more tailored manage of expectations as well as strategies to enhance the therapeutic relationship in certain clients are identified as the two key elements in order to improve the dropout in IBTs. Going further, in the mid and long run, ideographic interventions would be vital. The present study permits to better grasp the phenomenon of dropout in IBTs and delineate specific implications both in terms of research, training and practice

Keywords: Transdiagnostic, Internet-based, Dropout, Consensual Qualitative Research, Adherence.

Introduction

Internet-based treatments (IBTs) have emerged as an innovative treatment approach designed to reduce the large number of untreated people suffering from different mental disorders (Andersson, 2016). Geographical, cultural, and social barriers can be overcome due to IBTs' ability to be implemented in multiple contexts, both community and clinical. A successful dissemination of IBTs would produce a more cost-effective relationship (Nordgren et al., 2014), leading to a significant reduction in the mental health care budget (McCrone et al., 2004). Apart from wide dissemination, IBTs can have a wide range of other advantages. In relation to client recruitment, online interventions can bring alternatives to people who avoid consulting a therapist for a number of reasons, such as stigmatization or other practical concerns. Thus, flexibility in establishing the framework for the therapy (in terms of space and time) is an evident facilitator of these kinds of treatments. In addition, it may be easier to assess clients in IBTs than in face-to-face therapy because better data monitoring can be carried out, as well as lower rates of missing data (Andersson and Titov, 2014).

In the past 15 years, a growing body of evidence has shown the efficacy of these types of treatments (Botella et al., 2000; Marks et al., 2004). IBTs have been found to be efficacious and effective for a wide range of disorders (for a review, see Andersson, 2016). Although more research is needed, in many cases these treatments are found to be equally as effective as face-to-face approaches (Andersson et al., 2014). Particularly in the field of emotional disorders (ED) (depression and anxiety disorders), which are the most prevalent mental disorders (Wittchen et al., 2011), different IBTs have been developed, with considerable evidence supporting their efficacy (Karyotaki et al., 2017; Olthuis et al., 2016).

Focusing on the dark side of the moon

Although IBTs' progress and promising future are undeniable, many aspects remain to be studied to conclusively show their effectiveness. Among them, negative effects are a vital factor. Negative effects have been studied within clinical psychology (Bergin, 1963), but only recently has emphasis been placed on determining how to prevent and correct failure in psychotherapy (Barlow, 2010; Lambert, 2010; Lilienfeld, 2007). Nevertheless, little research has been carried out on the negative effects of Internet interventions (Rozental et

al., 2015). A recent meta-analysis showed that among the total number of analyzed clients who received Internet Cognitive Behavior Therapy (ICBT), 5.8% experienced deterioration (Rozental et al., 2017).

Likewise, an important concern about IBTs is related to the high rates of non-adherence to these protocols (Christensen et al., 2009; van Ballegooijen et al., 2014). Dropout rates have consistently been found to be higher in non-guided IBTs than in guided ones (e.g. Andrews et al., 2010; Richards & Richardson, 2012). However, previous meta-analyses yielded average dropout rates of around 20% in guided IBTs for emotional disorders (e.g., Andrews et al., 2010; van Ballegooijen et al., 2014), suggesting that there is still considerable room for improvement in this regard. Consequently, adherence in general and treatment dropout in particular should be studied in order to establish the main stumbling blocks in implementing IBTs, and identify potential profiles of patients who might benefit from these treatments, compared to other profiles that could respond adversely to them.

Undoubtedly, client characteristics are of vital importance in conducting an in-depth study of potential barriers to the success of a certain psychotherapeutic approach (Bohart and Wade, 2013). Conclusive evidence supports that the less adherent a client is, the worse the treatment outcomes are (Vermeire et al., 2001; Taylor et al., 2012), what has been specifically studied in IBTs (Donkin et al., 2011). In this regard, dropping out has consistently been identified as a predictor of failure in all the possible dimensions of psychotherapy outcomes. For instance, in terms of symptomatology, dropout is associated with less remission and greater worsening of symptoms (McIvor et al., 2004; Reis and Brown, 1999).

Characteristics associated with patients are numerous, such as readiness to change or client expectations. Expectations are not only an important issue in terms of their direct relationship with outcomes (Constantino et al., 2011), but also due to their link with early termination or dropout, although more evidence is needed about this finding. However, studies have shown that clients who do not believe in the treatment's rationale are more prone to dropping out (Westmacott et al., 2010), and that educating patients about the expected length of the treatment may decrease the dropout rate (Swift and Callaghan, 2011).

Clients' experiences of dropout in IBT

Although many qualitative studies do examine client experiences from a qualitative perspective (e.g. Knowles et al., 2014), only few have posed the question on the experience of dropping out an IBT (e.g. Johansson et al., 2015). To date, the most common approach used in the research on IBT dropout has been based on quantitative methodologies, particularly regarding the study of predictors (e.g., Alfonsson et al., 2016; Högdahl et al., 2016; Karyotaki et al., 2015; Melville et al., 2010).

Examining clients' experiences from a qualitative perspective may provide more in-depth and clearer answers about the complexity of treatment dropout. Among the wide range of qualitative methodologies, Consensual Qualitative Research (CQR) (Hill et al., 2005) has been shown to be useful for several reasons. First, as in Grounded Theory, there is a data analysis protocol that provides a clear and precise way of analyzing the raw data (McLeod, 2013). Additionally, CQR has been developed by psychotherapy researchers, which makes this approach a particularly suitable tool for any study within the field. Finally, CQR is based on consensus as its defining characteristic, which makes it a very attractive methodology for working in teams with different levels of experience, from PhDs to graduate students. CQR, unlike phenomenological approaches that focus only on descriptive analysis, includes interpretation as a way of unraveling the core meaning of clients' or therapists' experiences (McLeod, 2013).

Thus, the aim of this study is to conduct a qualitative analysis of the subjective experience of a sample of patients who dropped out of a transdiagnostic IBT for emotional disorders.

Methods

Sample

Ten patients (8 women, 2 men) who dropped out of a transdiagnostic IBT participated in the study. The participants ranged in age from 21 to 59 years old (Mean = 35.4, Standard Deviation = 13.4). Demographic and clinical characteristics are depicted in Table 6-1. The sample was selected by convenience and was obtained from two randomized controlled trials (RCT) that are currently being conducted.

Treatment

Transversal is a transdiagnostic IBT developed by Labpsitec. The protocol consists of 12 modules, and participants are encouraged to complete one module per week. Two RCTs are being conducted using the protocol. The purpose of one of the RCTs is to analyze the effectiveness of a transdiagnostic IBT compared to treatment as usual as provided in the Spanish public mental health care system (González- Robles et al., 2015). The other RCT seeks to study the differential efficacy of a transdiagnostic IBT that includes a treatment component to enhance positive affectivity in a community sample. In this protocol, the contents are organized in 16 modules (Díaz-García et al., 2017). These two studies have three important characteristics in common: 1) Both treatments target ED, namely, major depressive disorder, dysthymic disorder, social anxiety disorder, generalized anxiety disorder, panic disorder, agoraphobia, obsessive-compulsive disorder, and not otherwise specified mood and anxiety disorders; 2) Both treatments are based on the transdiagnostic approach to the treatment of ED (Barlow et al., 2004) for which several studies have shown its the efficacy and effectiveness in improving symptomatology, functionality, quality of life, and emotion regulation skills of patients with emotional disorders in both naturalistic and randomized controlled trials (RCTs) (Dear et al., 2011; Farchione et al., 2012; Johnston et al., 2011; Titov et al., 2013); and 3) Both treatment protocols are web-based, self-administered treatments with minimum contact/support from a therapist that consists in a weekly phone call lasting 5 to 10 min to each participant. These calls aim to resolve technical difficulties or doubts about the use of the protocol and to encourage the participants to continue doing it. Besides, a non-human support is delivered through two weekly mobile phone text messages that are automatically sent and aim to remind the participants of the importance of reviewing the modules as well as doing the homework tasks.

Table 6-1. Demographic and clinic characteristics of the 10 participants

P	G	Age	Marital status	Educat.	PD	CD	BDI-II ^a	OASIS ^b	QLI ^c	MOD
#1	F	23	S	1	OCD	2 (DD, AD)	8	8	8.4	4
#2	M	27	S	3	AD	1 (PD)	8	8	7.6	4
#3	F	45	M	2	SAD	2 (MDD, GAD)	37	12	3.5	5

#4	F	60	D	2	MDD	1 (GAD)	25	1	2.7	9
#5	F	28	S	3	MDD	2 (SAD, GAD)	38	11	3	3
#6	M	23	S	2	MDD	1 (PD)	33	9	4.5	3
#7	F	24	S	4	AD	1 (MDD)	25	13	4.9	5
#8	F	40	S	2	SAD	1 (MDD)	42	20	2.6	3
#9	F	35	D	3	GAD	1 (MDD)	52	12	2.8	8
#10	F	61	M	3	GAD	1 (PD)	40	14	5.5	4

Note: P: Participant; G: Gender: F (Female), M (Male); Marital status: S (Single), M (Married), D (Divorced); Educat.=Education: 1 (Basic), 2 (Secondary studies), 3 (University studies); PD: Principal diagnosis; OCD: Obsessive-compulsive disorder; AG: Agoraphobia; SAD: Social anxiety disorder; MDD: Major depressive disorder; GAD: Generalized anxiety disorder; DD: Dysthymic disorder; PD: Panic disorder; CD: Comorbid diagnoses; QLI: Quality of Life Inventory; MOD: Number of completed modules.

a Beck Depression Inventory (BDI) (Beck et al., 1996)

b Overall Anxiety Severity and Impairment Scale (OASIS), (Norman et al., 2006).

c EuroQoL-5D questionnaire (EQ-5D), (Badía, 1999).

Procedures

Overall, participation was offered to 18 individuals who dropped out of these two RCTs. Out of the total 18, 10 agreed to participate in the study. The 8 participants that were offered to participate and declined, adduced the following reasons: 5 did not have time, 2 were not interested in the study and 1 participant firstly accepted but then was not reachable so after 3 attempts it was decided to find a new participant. The contact was made by phone calls. Eligibility criteria included:

a) providing written, informed consent, and b) having dropped out of the treatment after completing a minimum of 3 modules. This criterion was established to ensure that every participant had at least minimally experienced the different aspects of the online intervention, in terms of clinical content, technical features, therapist support, personal aspects, and so on. The study was approved by the ethics committee of Universitat Jaume I.

Five interviews were conducted face-to-face in the laboratory, and the other five were conducted via videoconference. Each interview lasted between 40 min and 1 h. All interviews were audio-recorded for transcription and subsequent codification. The interviews were transcribed verbatim (except for

minimal silences or stutters) for all participants. At the end of the interview, all the participants received a monetary compensation of 15 € for their participation.

Characteristics of interviewers, judges, and auditor

Three graduate students (two males and one female) interviewed participants and served as judges on the primary team. A full professor in psychology served as auditor. All of them are authors of the study. Two of the graduate students had completed a course in qualitative research where CQR was addressed. The senior researcher is a leading researcher in the field of Internet interventions. Thus, the primary team had strong support in discussing the contents, in terms of their involvement in the field of Internet interventions.

Two of the interviewers (ADG & AGR) had previous knowledge of the participants as the sample was recruited from the respective trials that each of them is in charge of. So as to ensure an unbiased procedure in the interviewing process, ADG only interviewed participants that took part of AGR trial and the other way around. JFA interviewed in- distinctly, as he did not have previous contact with the participants. Besides, it must be mentioned that the study was conducted as the master thesis of the first author (JFA).

Interview protocol

A semi-structured interview with open-ended questions was designed, following the principles specified in the CQR guidelines (Hill et al., 2005). As in many other qualitative interviewing processes, the main purpose of the CQR is to gather information that is as diverse as possible within certain thematic areas. The CQR is considered a relevant first step that may highly coincide with the subsequent domains (Hill et al., 2005).

As in other semi-structured interviews, the main aim is to delve into the client's subjectivity while not moving outside certain boundaries (related to the questions) that may help, afterwards, to compare the data obtained from all the participants (Knox and Burkard, 2009).

For this study, the interview construction process included initial discussion among the primary team. The second step was the elaboration of the questions by the three graduate students, and separately by the full professor. Finally, agreement was reached by comparing the two lists of questions, trying to balance the greatest number of topics with the least number of questions.

Data analysis

As described above, CQR was applied to analyze the narrative content. The CQR's structure includes two essential aspects. The first is to set up a team with at least three members, the auditor and two judges. These roles can be interchangeable, as in the present study. The second main aspect is to follow specific steps to establish the domains, the core ideas, and the cross categories.

To report the study, the Consolidated criteria for reporting qualitative research (COREQ), proposed by Tong et al. (2007), were followed (see Supplementary Table 1: [https:// doi.org/10.1016/j.invent.2017.09.001](https://doi.org/10.1016/j.invent.2017.09.001)).

The procedure consisted of audiotaping, transcribing, and coding the interviews.

The categories were labeled general if they applied to all ten cases, typical if they applied to at least half but not all of the participants (5 to 9), and variant if they applied to less than half (1 to 4).

Results

Domains, categories, and illustrative core ideas make up the three aspects of the CQR. In all, 22 categories were found, 3 of which were general, 5 typical, and 14 variant. Table 6-2 shows the results of the qualitative analysis.

Past experiences with psychotherapy

Past experiences with psychotherapy include any form of psychological assistance received by the participants, regardless of the context, the duration, or the format. Previous treatments of close relatives or friends were also taken into consideration because these types of indirect experiences may also have some kind of influence on the patient's representations (such as motivation, expectations, or attitudes toward therapy). The diverse experiences expressed by the patients were classified in three categories: positive, negative, and ambivalent.

Positive (Variant): This category refers to the fact that the clients experienced past psychotherapies as something that helped them. For example, one participant (#8) claimed:

Interviewer: Regarding your experience, how was it?

Participant: Completely positive. Positive. He was a cognitive behavioral therapist. That was his framework. For now, I had to quit because currently I am not working, and I couldn't afford the treatment. I had gone to around 15 sessions, one per week. The therapist was an essential part of that treatment.

Interviewer: Sure. He helped you.

Table 6-2. Domains, categories and illustrative ideas of the 10 participants

Domains	Categories/(frequency)	Illustrative core idea
Past experiences with psychotherapy	Positive experiences <i>Typical</i> (5)	All previous therapies had helped the P
	Negative experiences <i>Variant</i> (3)	P expresses that he just talked about how in the past week had not had any guidelines to follow
	Ambivalent experiences <i>Variant</i> (2)	P claims that maybe the therapy she received in the past was appropriate, but she didn't like the kind of interaction she had with the therapist
Reasons given for dropout	Insufficiently addressing the client's concerns <i>Variant</i> (4)	The program did not provide the P with specific information about her problems
	Logistic reasons <i>Variant</i> (2)	P moved to another country where he did not have Internet connection
	Low levels of supportiveness <i>Variant</i> (2)	P needed more contact with a therapist
	Ineffectiveness of the treatment <i>Variant</i> (2)	P expressed that the treatment was not working on him/her
Expectations before receiving an online treatment	Negative <i>Variant</i> (4)	P was not confident that a machine could help her
	Positive <i>Variant</i> (3)	P says that he started the treatment thinking that the online therapy would help
	Ambivalent <i>Variant</i> (3)	P said that he did not have any particular expectations about the online treatment
Facilitators of online therapy	Specific elements of the online treatment <i>Typical</i> (8)	P said that the contents were very well organized
	Flexibility <i>Typical</i> (7)	P states that it is not necessary to follow any specific schedule

	Dissemination <i>Variant (3)</i>	P states that it can be useful to reach more people in a more economical way
Barriers to online therapy	Lack of individualization <i>General (9)</i>	P says the treatment would have worked if it had been more personalized
	Feedback from the therapist <i>General (9)</i>	P highlights that the therapist did not tell her whether she was progressing well or not
	Technical aspects <i>Variant (4)</i>	P complains that videos load slowly
	Lack of supportiveness <i>Typical (7)</i>	P feels that the online treatment is cold and impersonal
Strategies to improve online therapy	Feedback from the online treatment <i>Variant (3)</i>	P states that the program did not give her feedback about what she was doing well
	Individualization of treatment <i>General (9)</i>	P states that the treatment should include more examples related to her problem
	Technical aspects <i>Variant (2)</i>	P expresses that the font used for the text was too small and basic
	Flexibility in the delivery approach <i>Typical (7)</i>	P states that the program should be more interactive
	Specific elements of the online treatment <i>Variant (5)</i>	P expresses that it would be useful to combine the online treatment with face-to-face sessions when necessary

Participant: A lot.

Negative (Variant): This category includes either psychotherapy experiences that did not work on the client (i.e. the fact that the patient experienced past psychotherapies as something that did not help him/ her) or explicit “negative aspects” (i.e. negative experiences stemming from either the characteristics of the therapy or the therapeutic relationship). Whereas a negative overall result of the therapy involves an objective or subjective feeling of deterioration, negative aspects could be part of a whole process whose final result may or not be adverse.

Participant (#3): “Actually, I didn't stay long in that therapy because I didn't feel good. I didn't feel comfortable enough with the therapist to open up.”

Ambivalent (Variant): Although this seems to be a straightforward issue, this is not the case because some answers are full of nuances. A client (#10) gives an illustrative example of how ambivalent an answer can be:

“Client: I have been once, actually twice, to a psychologist. The first time was many years ago (15 or 18 years ago) due to problems related to my job. The second time was when I was referred to this study. Before coming here, I had been to a psychologist who talked to me about the study. I didn't stay long in the therapy because I didn't have enough trust in the psychologist to open up to him. There are people you talk to and you notice that you can rapidly trust them. But I didn't feel comfortable with him. He didn't even talk much. I used to arrive at his office, and I started giving my speech. He just said: “all right, see you next week”. If therapy is for that, I have friends, you know? Maybe it was the appropriate therapy, but I didn't like to have that kind of interaction.

Interviewer: So, if you had to say whether your general experience with the therapy was positive or negative, what would you say?

Client: Positive.

Interviewer: You can be absolutely honest.

Client: Yes, it was positive. I would tell you otherwise.”

Reasons for dropout

All the patients talked about the reasons that led them to drop out of the online treatment. It must be mentioned that the principal aim of the study was not only to examine the reasons clients dropped out, but also to look into the

feelings and experiences they had during the treatment. Three categories emerged from the interviews:

Logistic reasons (Variant): This category encompasses space and time limitations, as well as Internet connection problems. One participant (#2) expressed it in these words:

“I couldn't finish the treatment because I moved to England for work reasons. In my room, I didn't have Internet connection”.

Insufficiently addressing the client's concerns (Variant): Referring to the fact that the online treatment was not able to provide answers to the participant's case-specific reasons for seeking help. As an example, participant #4 concluded:

“I needed a therapy that could better address what I felt. It didn't give me a specific answer to my worries”.

Low levels of supportiveness (Variant): i.e. referring to the reduced ability of online therapy, compared to face-to-face therapy, to make the patients feel protected, understood, and listened to. A client (#1) expressed it in the following way:

“From my point of view, the contact with the therapist was an essential aspect of therapy. Therefore, I lost all my interest in the therapy and didn't want to continue”.

Ineffectiveness of the treatment (Variant): This category includes those participants who stated that the treatment was not working on them. Some put this into words in the following way (participant #8):

“I was feeling that the therapy wasn't going to help me with my problems. I thought it could lead me to be even more anxious and that it wasn't going to be beneficial for me. So, I felt that I was going to waste my time if I continued”.

Expectations before receiving the online treatment

Three main categories were found within this domain: Positive expectations, Negative expectations, and Ambivalent or Neutral expectations.

Positive (Variant): This category captures all the patients who started with high expectations.

Negative (Variant): By contrast, this category captures all the answers referring to low expectations.

Neutral/Ambivalent (Variant): Neutral refers to expectations that cannot be identified as either positive or negative, whereas ambivalent is a mixture of both positive and negative feelings. An illustrative example of this ambivalence is shown in the following extract (participant #5):

“I called and I was told that face to face therapy... Is it called that? That face to face therapy was full and a new method was being launched and being offered... this online therapy... Well, to be honest at the beginning I was... I was reluctant because I was aiming to talk with someone (a therapist) and explain to them what I was feeling and what I was experiencing. But I thought to myself... it may be OK, I will try, it might be OK... That's why I accepted, and I started the treatment”.

Within these categories, some trajectories could be identified comparing the beginning of the treatment and the course of the treatment. The trajectory is relevant because it can reflect changes during the treatment, which is probably the most decisive aspect when considering expectations in different contexts, but also in psychotherapy. Three trajectories were identified: a) Some clients tend to worsen their initial positive expectations; b) Others start and finish with low expectation levels; and c) Others start and finish with positive expectations. As an illustrative example of the first trajectory identified, a client (#1) used the following words:

“I had great expectations, but I was disappointed. I would call it “the collapse of a myth””.

Perceived facilitators of online therapy

In this domain, clients were asked about the advantages of Internet-based treatments in order to identify the perceived benefits. Three categories were created within this domain.

Flexibility (Typical): Participants referred to aspects of the online treatment that provide more adaptability, such as accessibility from anywhere and at any time. Some participants valued the fact that they did not need to follow a specific schedule, and also that this kind of therapy was much less time-consuming than other formats such as individual face-to face treatments.

Specific elements of the online treatment (Typical): Aspects associated with the contents (e.g. techniques, exercises, or clinical vignettes) or the format (e.g. videos) of the treatment. In this regard, some clients felt that the contents of the therapy were very well organized, that the intervention was adequate, and

that it also allowed them to make their own self-assessment. The following example illustrates this category (participant #9):

“Interviewer: Can you tell me a little bit about your experience with the online treatment?”

Client: My experience... In general, I am satisfied because I think the online treatment we are talking about was... it was well done... I mean, the treatment properly addressed topics like emotions, assertiveness, and so on...The tasks were also very well organized, and the questionnaires were really useful because you can see your results instantly... In general, it was a good experience.”

Dissemination (Variant): The last category that emerged in this domain referred to the potential of IBTs to reach more people in a more cost-effective way.

Barriers to online therapy

One of the main aims of this study is to delve into obstacles perceived by clients who dropped out; therefore, a central domain to examine was Barriers to online therapy. It could be of paramount importance in helping to explain what might interfere with IBTs' acceptance, implementation, and, finally, effectiveness. Four main categories stemmed from this domain:

Lack of individualization (General): This category included all the illustrative core ideas related to the therapy's inability to address the client's specific concerns, symptoms, problems, questions, or doubts. That is, a lack of tailored or personalized interventions. All the patients mentioned this category as a major shortcoming of this kind of approach. An example provided by a participant (#1) was:

“Interviewer: Do you think IBTs can work? Client: No. Based on what I think, no.

Interviewer: Why?

Client: Just because of it. Let's see, everything is too general, and it's a very important factor. Those of you who do believe in these kinds of treatments should take into account that not everyone is the same. So, some people may need more treatment, others less. For example, emotion regulation, which is what the treatment was based on... not everyone functions in the same way.

Interviewer: Mhm...

Client: Yeah, it's too general. Everyone... Emotion regulation. Some common standards are applied to everyone. Maybe I am a weirdo, I don't know.

Interviewer: No, of course not. That's your opinion and it's valid.

Client: So, summarizing my idea... I think the treatment was too general, and not everyone is alike or at the same level.”

Feedback from the therapist (General): This category involves the transmission of evaluative or corrective information given to the client in an unsystematic way, rather than using some kind of routine outcome monitoring assessment, as Lutz et al. (2015) described. The following extract illustrates this category:

“Interviewer: Did you feel the need for therapist contact while you were receiving the online treatment?”

Client: Well... I think I need to be in contact with a professional very often because I tend to... I don't know the proper words, but I tend to become unstable quite often. I mean... to become unstable because I feel depressed, and I need a professional to tell me: “This happened because of that”, “don't worry because nothing is wrong”.

Interviewer: So, you mean that the online treatment did not fulfill that need.

Client: No, it didn't. I've told you about it before. There are very different kinds of people. There are people who know how to solve their doubts, but people like me need someone to tell us “you are wrong”, “you are making a mistake”. Maybe it is a lack of maturity, I don't know...”

Lack of supportiveness (Typical): All the statements about problems due to the lack of a therapeutic bond were classified within this category.

One participant (#8) stated this clearly:

“Apart from advice you are provided... It is as I said before, it is necessary to have a therapist behind to push you a bit, to give support, to encourage you. That's very important, extremely important. Otherwise I don't think I could benefit from a treatment.”

Feedback from the online treatment (Variant): As some of the participants stated, online treatments can lead to less involvement by the clients due to the lack of regular contact with a therapist. Thus, some of them stated that it was an

obstacle that the treatment itself did not provide more feedback on the exercises, as well as on their progress.

Technical aspects (Variant): This category assembles all the difficulties encountered by the participants in the use of the system. An illustrative example of this is expressed by a participant who said that “videos were too slow”. Other features are more related to the difficulty of following the materials due to the density of the text.

Strategies to improve online therapy

This is the last domain identified within the interviews, and it refers to possible strategies to improve clients' adherence to treatment and, thus, reduce dropout rates in these kinds of interventions. In this domain, participants described four main categories. Logically, this domain is consistent with the Barriers domain because many of the perceived limitations of the treatment are addressed in this domain as possibilities for improvement in the future.

Individualization of treatment (General)

As in other domains, such as Barriers and Reasons for dropout, lack of individualization is the most compelling issue to address in IBTs. Hence, some participants express the need for treatments that can adapt their contents to specific needs, particularly matching the content of the modules to their specific cases.

Technical aspects (Typical)

It was consistently found throughout the interviews that some participants were not satisfied with the system. This can definitely be improved in the future, as long as technology continues to develop. Some of the ideas expressed by the patients are related to the presentation of the content, such as increasing the dynamic aspect by including more videos, or presenting texts in a more attractive way.

Flexibility in the delivery approach (Typical)

This domain contains aspects that may help to improve the treatment and features of the way it is delivered. For instance, a client stated that it would have been better if he had received the IBT combined with face-to-face sessions when necessary.

Specific elements of the online treatment (Variant)

In line with the obstacles related to the contents or delivery formats of these contents, participants defended the need to find a way to improve these kinds of treatments. Clients also mentioned the importance of increasing the interaction with the program as a way of enhancing treatment adherence.

Discussion

This study analyzes clients' experiences in the process of dropping out of an Internet-based treatment. Although Internet-based treatments have been shown to be effective, only a few studies have focused on potential barriers to their implementation (e.g. Montero-Marín et al., 2015) and possible negative effects (e.g. Rozental et al., 2017). Hence, qualitative research is a useful tool with which to reflect on this topic in an exploratory way (McLeod, 2013). In general, the answers given by the clients express important commonalities that may contribute to research and practice.

First, it should be mentioned that all the participants had previous experiences with psychotherapy. Positive, negative, and ambivalent experiences emerged as categories, and so no pattern was identified in this domain. Although in all cases these previous experiences were in face-to-face approaches, previous findings suggest that even clients with experience with an IBT would prefer face-to-face therapy if they could choose between these two delivery methods (Wallin et al., 2016). In any case, the novelty of IBTs is a key aspect when evaluating this approach because patients who enter the treatment may be uncertain about the unknown or have unrealistic expectations about what the treatment entails. Expectations, in any kind of therapeutic process, are thought to play an instrumental role in the treatment outcome (Constantino et al., 2011). In this regard, some authors have suggested that more emphasis should be placed on the management of expectations in these types of treatments (Ekberg et al., 2016; Montero-Marín et al., 2015). Thus, therapists in charge of admitting new clients to IBTs should thoroughly describe the implications and potential of the treatment. Because expectations have been found to be a key predictor of adherence to Internet interventions (Beatty and Binnion, 2016), the way therapists manage them should be taken into consideration.

Although scant research has examined specifically non-adherence from a qualitative perspective, prior research also emphasized expectations,

suggesting that they may have an influence on adherence (Johansson et al., 2015).

Therapists should capitalize on providing reasonable and realistic therapeutic rationales. Thus, it might be worthwhile to apply a stratified strategy, depending on the clients' profiles. Currently, all admissions are carried out equally, regardless of their socio-demographic or clinical characteristics (e.g. Díaz-García et al., 2017, González-Robles et al., 2015). Taking into account previous research on dropout in IBTs and socio-demographic characteristics such as being male or having low educational levels (Beatty and Binnion, 2016; Karyotaki et al., 2015), or clinical characteristics such as personality traits (Högdahl et al., 2016), or comorbidity with anxiety symptoms (Karyotaki et al., 2015), specific types of treatment introductions and better expectations management could be carried out. Previous research in this regard for face-to-face approaches has shown that it is possible to start making a systematic use of the available data in order to customize the treatments (Rubin et al., 2016; Zilcha-Mano et al., 2016).

It is also important to take into account not only the expectations at the beginning of the treatment, but also their tendency to change during it. Therefore, both perspectives should be considered. The former perspective expresses to what extent clients expect the treatment to be beneficial for them in solving the problems that motivated them to seek help. The latter is important to examine how the client's expectations can interact with the course of the treatment. In this regard, in a face-to-face approach, therapists can foresee the wide range of feelings, thoughts, desires, and needs of the patients and deliberately intervene in an appropriate way (Lambert, 2013). Although the type of IBTs used for this study only involves minimal support by a therapist as explained in the methods, exploring whether the treatment meets the client's expectations is an important issue because it could increase adherence. In fact, as the results show, three trajectories were identified. The three cases where expectations did not decrease (#2, #6 and #9) are consistent with those whose reasons for dropout were not related to limitations of the treatment protocol, but rather to logistic reasons. Hence, the way therapists introduce an objective picture of potential advantages and limitations of the treatment becomes important in producing reasonable expectations in the client.

The analyzed interviews also reveal that the main Reasons given for dropout by the patients overlap with the perceived Barriers of the online

treatment and with the Strategies to improve online therapy. All the ideas captured in these domains highlight a major drawback in the process of building the therapeutic alliance in IBTs. All the participants clearly identify the common feature of the absence of a therapist. Clients tend to compare this situation to traditional face-to-face approaches, which they find substantially more positive in this regard.

Nevertheless, different perspectives are identified related to this issue. Whereas some clients mention a lack of individualization of the treatment as a major drawback, which is consistent with previous research (Montero-Marín et al., 2015), others put a greater emphasis on the lack of supportiveness. The former is associated with the content received during the treatment that may not target the specific problems of the participants, whereas the latter is related to the lack of affective and personal contact with the therapist.

The reasons to understand why the clients express a lack of individualization are twofold. First, the online platform provides a non-interactive treatment, and thus the clinical examples and exercises are not adapted to the patient's clinical or socio-demographic characteristics. Second, the protocol implemented is based on a transdiagnostic approach that seeks to deliver the same treatment for different clinical symptoms (all ED). Although there is a strong and supported psycho-pathological rationale for its use (Harvey et al., 2004), as well as conclusive evidence of its efficacy and effectiveness both for traditional and online therapy (Andersen et al., 2016; Newby et al., 2015; Newby et al., 2016; Păsărelu et al., 2017), it may constitute a barrier to deliver more personalized contents.

With regard to the lack of supportiveness, it is evident that it is related to the minimal human contact provided by the treatment. In this sense, whereas an enhanced personalization can potentially be improved by further developing cutting-edge technology (e.g. tailored contents using algorithmic strategies), there is controversy about whether a strong affective relationship can be deployed at all through an IBT approach (Berger, 2017). There is even controversy about the relationship between therapeutic alliance and the outcome in IBTs. The existing data on this issue are contradictory (Sucala et al., 2012), unlike face-to-face therapy, where it is a robust predictor of change, accounting for 0.27 of the variance (Horvath et al., 2011). When considering therapists' perspectives of the importance of the therapeutic alliance in e-therapy, the answers show that they consider the therapeutic alliance to be an extremely

important aspect, both in face-to-face treatments and IBTs. However, as shown by previous research, therapists do not feel confident about their ability to build a strong alliance within an IBT (Sucala et al., 2013).

Accordingly, much more research shall be conducted to better elucidate how alliance, outcome and other explanatory variables may interact in IBTs. To do so, it should be taken into account the abundant existing research in this regard for face-to-face therapies throughout decades (e.g. Muran and Barber, 2010; Rossetti and Botella, 2017). In fact, both face-to-face approaches alliance (Sharf et al., 2010) and poorer alliance expectations (Zilcha-Mano et al., 2016) were found to be predictors of dropout.

All in all, these points are summarized in a specific example given by a participant (#4):

“Well, I start very motivated. Maybe only due to my need to improve. When I am not doing well, I always look for alternatives, different kind of alternatives. I got interested in this treatment due to its novelty. And it was working on me, but I encountered a machine, time and again. I needed a person. I needed the therapeutic relationship.”

This 60-year-old woman dropped out in module 9, after completing 75% of the program. In her case, expectations were high, and her motivation was evidently high. Likewise, she was considered to be improving throughout the treatment. Nevertheless, the weakness of the therapeutic relationship was a decisive aspect in her decision to drop out. While the perceived necessity of a therapist may be undeniable, it is also possible to consider that the experience and the reasons for early withdrawal could be influenced by the syndrome treated. It may be the case that a depressed patient is more prone to procrastination or an anxious patient is more sensitive to interpret experiences of exposure as adverse events.

Results also indicate the presence of facilitators of online therapy within the domains. However, according to our results, none of these facilitators was sufficiently decisive to keep clients from dropping out. Although it seems rather logical, it can be argued that if more facilitators were provided, dropout rates could decrease, even if barriers were still perceived. This hypothesis relies on basic decision-making theory and classical conditioning theory, which support the idea that people are influenced by gain-loss effects (Hastie and Dawes, 2010) and conditioned by positive reinforcement and punishment (Skinner,

1958). Moreover, categories such as Flexibility can be perceived as positive by clients, which is consistent with previous studies exploring the motivations to persist with IBTs (Wilhelmsen et al., 2013). In order to improve the design and implementation of these treatments to reduce non-adherence and maximize effectiveness, clients' experiences can provide an insightful perspective. In this regard, and consistent with the need for more personalized treatments, clients expressed the importance of matching the participant's answers to the program's contents. Similar to face-to-face approaches, if technological advancements make it possible, algorithms to generate expected outcome curves could make useful contributions to personalizing program contents and to better specifying all assessment processes (DeRubeis et al., 2014; Delgadillo et al., 2016). That is, principally permitting an interaction between clients' initial assessment and their evolution with the treatment's content. The potentialities of applying complex statistical developments and data mining techniques may provide with vital answers for IBT's delivery (Mohr et al., 2013). A well-developed example is an emerging mobile phone intervention design, called the just-in-time adaptive intervention (JITAI; Nahum-Shani et al., 2014). In this sense, some initial progress has been made with online assessment and diagnostic system within a web-based population and even with regard to post-treatment attrition and its predictors (Al-Asadi et al., 2014, 2015).

Study limitations

First, although this limitation is shared by most qualitative studies, the retrospective answers given by participants are a major methodological limitation. Retrospective recollection of experiences is subject to strong biases depending on the participant's awareness of the past event. Moreover, the way clients express these recalled ideas can also be inaccurate or conflict with their inner thoughts. In addition, the data obtained rely only on participants' willingness to disclose information. Thus, the interviewer's ability becomes a key aspect in qualitative approaches (Knox and Burkard, 2009). Another issue is that a convenience sample was recruited. It must be mentioned that clients who were reached and did not agree to take part in the study may have expressed different ideas about their adherence experience that would also be worth investigating. Nevertheless, representativeness in qualitative research is not equally determinant as in quantitative research. The key feature for qualitative research is data saturation which means that data collection should be in pursuit until no new conceptual insights are generated. In the case of this study the last

analyzed interview did not produce an increase in the number of domains, so no more interviews were conducted. Besides, with regard to the sample size, CQR guideline were followed which recommends samples of 8–15 participants.

Future directions

It would be quite useful to examine the experiences of clients who finished the whole treatment. Completers can be divided into two main groups. On the one hand, some participants show significant improvements on the pre-post treatment measures. On the other hand, some participants either do not improve, or they even deteriorate. By describing successful treatments, these participants may shed light on the key factors that contribute to producing client change. Regarding completers who showed worsening, it would be relevant to differentiate reasons for dropout from iatrogenic components of the treatment. Previous studies may contribute to addressing these further questions (e.g. Donkin and Glozier, 2012; Wilhelmsen et al., 2013).

It is also important to take into account therapists' experiences at different care levels, such as primary care settings (Gellatly et al., 2017; Montero-Marín et al., 2015), specialized care (Gellatly et al., 2017; Kivi et al., 2015) and rural contexts (Sinclair et al., 2013). Adherence depends not only on the client's willingness to take part in these kinds of treatments and on the specific contents of the treatments, but also on the clinician's perspectives and active involvement.

Implications for practice, training, and research

In terms of practice, the use of IBTs in general, and transdiagnostic IBTs in particular, is expected to increase within the mental health field, particularly in public health systems, such as the IAPT in UK (NICE, 2009). Thus, one of the most relevant aspects to take into consideration is therapist training. Even in self-guided treatments, some kind of support is always provided. Therapists giving support should be trained to better introduce the program. This key aspect may lead to better management of expectations, which, in light of previous studies and consistent with our results, may play an instrumental role in clients' adherence. In addition, these types of studies should include patient's suggestions in future research designs in order to better address an unattended aspect of Evidence Based Practice (Swift and Greenberg, 2015). To achieve this aim it must be essential to incorporate the already developed lines on user-centered designs (De Vito Dabbs et al., 2009), person-based approaches

(Yardley et al., 2015) or practice oriented research (Castonguay et al., 2013), all facets that incorporate the needs of all stakeholders.

Finally, the study may also contribute to the discussion about adverse effects in IBTs (Rozental et al., 2017), emphasizing the need to further develop this line of research.

Conclusion

It is doubtless that more personalized treatments shall be delivered to increase adherence rates. Thus, there is a clear need to determine for whom IBTs may work as well as any other psychotherapeutic intervention (Norcross and Wampold, 2011), carrying out more studies on moderators, mediators, and mechanisms of change (Mogoase et al., 2017). It is essential to continue the development of systems and platforms that can reproduce therapeutic settings as closely as possible (Andersson and Titov, 2014) and address patients' specific needs. In fact, Internet interventions were initially designed to provide with personalized treatments (Andrews and Williams, 2014), in other words, to better adapt the contents of the treatment to the needs of the client. As Kazdin and Blase (2011) point out, a great effort should be made to find a balance between effectiveness and dissemination, but without ignoring the client's preferences (APA, 2006). To achieve that aim it will be indispensable to integrate unconnected research lines such as IBTs and Ecological Momentary Assessment under a common conceptual model (Mohr et al., 2014). All in all, IBT, as a research area, is still in its infancy. Hence, many aspects will require study in the near future, in order to develop a promising field that can be a key tool for coping with current mental health challenges.

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Conflict of interests

The authors declare that they have no competing interests.

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Chapter 7: Positive and Negative affect Schedule (PANAS): psychometric properties for the online version in a Spanish clinical sample with emotional disorders

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Positive and Negative Affect Schedule (PANAS): psychometric properties for the online version in a clinical sample with emotional disorders

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Abstract

Introduction. The Positive and Negative Affect Schedule (PANAS) is the most widely and frequently used scale to assess positive and negative affect. The PANAS has been validated in several languages, and it has shown excellent psychometric properties in the general population and some clinical samples, such as forensic samples, substance users, and adult women with fibromyalgia. Nevertheless, the psychometric properties of the scale have not yet been examined in clinical samples with anxiety, depressive, and adjustment disorders. In addition, the proliferation of Internet-based treatments has led to the development of a wide range of assessments conducted online, using digital versions of pen and paper self-report questionnaires. However, no validations have been found that analyze the psychometric properties of the online version of the PANAS. The present study investigates the psychometric properties of the online Spanish version of the PANAS in a clinical sample of individuals with emotional disorders.

Method. The sample was composed of 595 Spanish adult volunteers with a diagnosis of depressive disorder ($n = 237$), anxiety disorder ($n = 284$), or adjustment disorder ($n = 74$). Factor structure, construct validity, internal consistency, test-retest reliability, and sensitivity to change were analyzed.

Results. Confirmatory factor analysis yielded a latent structure of two independent factors, consistent with previous validations of the instrument. The analyses showed adequate convergent and discriminant validity, good internal consistency, and test-retest reliability, as well as sensitivity to change.

Discussion. Overall, the results obtained in this study show adequate psychometric properties for the online version of the PANAS as a measure for the assessment of positive and negative affect in a Spanish clinical population.

Introduction

The study of the structure of affect has had particular importance in the psychopathological and clinical knowledge about mental disorders, and it plays a central role in human experience (Gray & Watson, 2007). The term affect has been used to indicate everything that is emotional, that is, sentiments, preferences, emotions, moods, and affective traits (Rosenberg, 1998; Gross, Sutton, & Ketelaar, 1998), and it is regarded as a psychological construct that refers to mental states involving evaluative feelings (e.g., to feel good-bad, to like-dislike a situation) (Parkinson, Totterdell, Briner, & Reynolds, 1996). Nevertheless, difficulties in achieving reliable measurements and the absence of a unified model of affective processes have hampered its scientific study (Lucas, Diener, & Larsen, 2003).

In recent decades, a growing number of studies have tried to investigate the structure of affect. Most of these studies agree that the affective experience has two dominant dimensions, namely, positive affect (PA) and negative affect (NA) (Russell, 1980; Zevon & Tellegen, 1982; Watson, Clark, & Tellegen, 1984). Based on the pioneering work by Bradburn (Bradburn, 1969), PA and NA were described as two independent unipolar dimensions of affect, including all those affective states with a positive valence (joy, enthusiasm, crush, etc.) and a negative valence (anger, fear, anxiety, etc.). Furthermore, in a re-analysis of a large number of affect studies, Watson and Tellegen (1985) concluded that the two main factors that appeared consistently were positive and negative affect, and they presented the consensual two-factor model. These two factors have been conceptualized as two independent and uncorrelated dimensions of affect (Watson & Tellegen, 1985). Whereas PA reflects the "extent to which individuals feel enthusiastic, active, and alert" (Watson, Clark, & Tellegen, 1988, p.1063), NA involves a variety of aversive mood states, such as anger, guilt, and fear. The data suggest that low levels of PA are related to and predict the onset of depression (Snyder & Lopez, 2009), and that high PA is associated with greater well-being (Fredrickson, 2001). By contrast, low NA indicates a state of calmness and serenity, whereas high NA is characteristic of anxiety (Watson et al., 1988). The two dimensions of affect (PA and NA) have been crucial in the conceptual differentiation between depression and anxiety disorders (Tellegen & Auke, 1985). In addition, PA and NA have also been strongly related to Extraversion and Neuroticism personality dimensions, respectively (Watson & Clark, 1992).

It is important to highlight that without an adequate and reliable measurement of affect, it is not feasible to conduct research that provides empirical support in this field. Thus, the Positive and Negative Affect Schedule (PANAS) was developed for this purpose. The PANAS is the most widely and frequently used scale to assess PA and NA. The original PANAS scale was designed by Watson et al. (1988) with the aim of obtaining a brief and easy to administer measure to assess positive and negative affect and, thus, obtain descriptors of affection that are as pure as possible. In this regard, the authors finally isolated 10 PA markers (PA subscale) and 10 NA markers (NA subscale), which constitute the 20 items on the current version of the PANAS. On the one hand, the PA subscale reflects the extent to which a person feels interested, excited, strong, enthusiastic, proud, alert, inspired, determined, attentive, and active. On the other hand, the NA subscale includes descriptors such as stressed, upset, guilty, scared, hostile, irritable, ashamed, nervous, jittery, and afraid. All the items are rated on a scale ranging from 1 ("very slightly or not at all") to 5 ("extremely").

Although the PANAS was initially designed and developed in North America (Watson et al., 1988), it has been validated in several languages in both in western (e.g. Italy: Terracciano, McCrae, & Costa, 2003; France and Canada: Gaudreau, Sanchez, & Blondin, 2006; Hungary: Gyollai, Simor, Koteles, & Demetrovics, 2011) and non-western countries (e.g. Turkey: Gençöz, 2000; Mexico: Robles & Páez, 2003; Korea: Lim, Yu, Kim, & Kim, 2010; Argentina: Moriondo, De Palma, Medrano, & Murillo, 2012; Brasil: Pires, Filgueiras, Ribas, & Santana, 2013; Africa: Merz et al., 2013; India: Pandey & Srivastava, 2016; Pakistan: Akhter, 2017). The results of these studies have shown excellent internal consistency and discriminant validity. In Spain, the PANAS has also demonstrated high internal consistency ($\alpha = .89$ and $.91$ for PA and NA in women, respectively, and $\alpha = .87$ and $.89$ for PA and NA in men, respectively) in college students (Sandín et al., 1999). Nevertheless, the PANAS has only been validated in the general population, both in its original version (Watson et al., 1988) and in the Spanish version (Sandín et al., 1999), as well as in the other previously mentioned countries. The only exceptions are some validations conducted with clinical samples, such as forensic samples (Leue & Beauducel, 2011), psychiatric outpatients (Lim, Yu, Kim, & Kim, 2010), substance users (Serafini, Malin-Mayor, Nich, Hunkele, & Carroll, 2016), and adult women with fibromyalgia (Estévez-López et al., 2016).

Currently, the proliferation of Internet-based treatments has led to the development of a wide range of assessments conducted online, using digital versions of pen and paper self-report questionnaires (Alfonsson, Maathz, & Hursti, 2014; Seib-Pfeifer, Pugnaghi, Beauducel, & Leue, 2017). However, although paper and online versions of the same instrument correlate strongly, they may differ in their psychometrics properties (Alfonsson et al., 2014). In this vein, the need for validated assessments applied online is increasingly evident (van Ballegooijen, Riper, Cuijpers, van Oppen, & Smit, 2016), reinforcing the importance of evidence-based assessment, that is, the use of research and theory in the selection of assessment targets, the methods and measures used in the assessment, and the assessment process itself (Hunsley & Mash, 2007). Given the key role of assessment in evidence-based practice, efforts to develop and promote rigorous assessment instruments are crucial for both researchers and clinicians involved in mental health. Thus, the validation of online scales can have a direct impact on the dissemination of evidence-based assessments because they can be applied more extensively.

Although the PANAS has been validated in the general population, the psychometric properties of this scale have not yet been examined in clinical samples with anxiety, depressive, and adjustment disorders. In addition, no validations have been found that analyze the psychometric properties of the online version of the scale. To the best of our knowledge, this is the first study to evaluate the psychometric properties of the PANAS administered online in a Spanish clinical population.

Current study

The present study investigates the psychometric properties of the online Spanish version of the PANAS in a clinical sample of individuals with depressive, anxiety, and adjustment disorders. Specific objectives on the current study are: a) to determine the factor structure of the scale; b) to assess the construct validity; c) to examine the scale's internal consistency and test-retest reliability; and d) to analyze sensitivity to change.

Method

Participants

The sample was composed of 595 Spanish adult volunteers (195 men; 400 women), with a mean age of 37.38 years (SD = 12.54; range: 18-76). Most of

the participants were married or living with a partner (n = 273; 45.89), and most had high-level studies (n = 352; 59.2%).

The patients' diagnoses were depressive disorder (i.e. major depressive disorder, dysthymic disorder, depression not otherwise specified) (n = 237), anxiety disorder (i.e. generalized anxiety disorder, panic disorder/agoraphobia, social anxiety disorder, obsessive-compulsive disorder) (n = 284), and adjustment disorder (n = 74). In addition, regarding the number of comorbid disorders, 35% of the sample presented at least one comorbid anxiety or depressive disorder. A detailed description of the participants' sociodemographic and clinical data is presented in Table 7-1.

Table 7-1. Sociodemographic and clinical characteristics of the sample

Age in years, Mean (SD)	37.35 (12.55)
Sex, n (%)	
Female	400 (67.2)
Male	195 (32.8)
Relationship status, n (%)	
Single	261 (43.9)
Married/de facto	273 (45.9)
Divorced	56 (9.4)
Widowed	5 (0.8)
Education level, n (%)	
Without studies	2 (0.3)
Basic	79 (13.3)
Medium	162 (27.2)
High-level	352 (59.2)
Diagnosis category, n (%)	
Depression	237 (39.8)
Anxiety	284 (47.7)
Adjustment disorder	74 (12.4)
Principal diagnosis, n (%)	
Major depressive disorder	222 (37.3)
Dysthymic disorder	11 (1.8)
Generalized anxiety disorder	121 (20.3)
Panic disorder/agoraphobia	32 (5.4)
Panic disorder	18 (3)
Agoraphobia	19 (3.2)
Social anxiety disorder	65 (10.9)
Obsessive-compulsive disorder	17 (2.9)
Anxiety NOS	12 (2)
Depression NOS	4 (0.7)
Adjustment disorder	74 (12.4)

Number of comorbid disorders

0	385 (64.87)
1	147 (24.7)
2	36 (6.1)
≥ 3	26 (4.4)

Symptom severity, Mean (SD)

PANAS-P	20.19 (6.91)
PANAS-N	29.07 (8.14)
BDI-II	25.41 (11.85)
PHQ-9	14.44 (6.06)
BAI	21.25 (11.50)
OASIS	9.55 (4.31)
NEO-FFI-N	31.57 (7.56)
NEO-FFI-E	21.96 (8.66)

Note. PANAS-P = Positive and Negative Affect Schedule - Positive Affect; PANAS-N = Positive and Negative Affect Schedule - Negative Affect; BDI-II = Beck Depression Inventory; PHQ-9 = Patient Health Questionnaire; BAI = Beck Anxiety Inventory; NEO-FFI-N = Neo Five-Factor Inventory - Neuroticism; NEO-FFI-E = NEO Five-Factor Inventory - Extraversion

Spanish translation of the PANAS

First, a native Spanish-speaker with knowledge of psychology and emotional disorders, translated the PANAS items from English to Spanish. Second, a Spanish-English bilingual speaker who was not familiar with the questionnaire conducted a back-translation from Spanish to English. The person involved in the translation process was a native English speaker who has been living in Spain for many years and is fluent in both languages. The two English versions were compared, and the Spanish version of the PANAS was judged to be an accurate translation of the original English version.

Procedure

The data on the participants in this study came from different research projects, based on self-applied online interventions conducted by the present research group. Participants interested in the studies contacted the person in charge of the Internet intervention and were assessed by phone to establish the diagnosis. All the participants were assessed with a structured diagnostic interview. The interviews lasted approximately an hour and were conducted by pre-doctoral students who had been fully trained for this purpose. Once the inclusion criteria had been confirmed, participants signed an online informed consent, and they were informed about the anonymity and confidentiality of the data provided. Data were gathered using an online battery of questionnaires (described below in more detail in the Measures section) applied over the

Internet through a web platform (<https://www.psicologiaytecnologia.com/>) designed by our research group, and filled in before accessing the treatment modules. A portion of the total sample completed the PANAS before and immediately after receiving the Internet-based treatment. All the research projects from which the sample was derived had been approved by the Ethics Committee at Jaume I University.

Measures

Diagnostic Interview

Mini International Neuropsychiatric Interview (Sheehan et al., 1998). The MINI is a short, structured, diagnostic interview for DSM-IV and ICD-diagnoses. This interview has excellent test-retest and inter-rater reliability ($k = .88-1.00$), as well as adequate concurrent validity with the Composite International Diagnostic Interview (Lecrubier et al., 1997). The Spanish validation was used in this study (Ferrando, Bobes, & Gibert, 2000).

Diagnostic Interview for Adjustment Disorders (Rachyla, Botella, Mor, Tur, Lopez-Montoyo, Baños & Quero, in preparation). This measure is a semi-structured interview based on the ICD-10, DSM-IV-TR, and Structured Clinical Interview for DSM-IV (SCID-CV) for the diagnosis of AD. It assesses the number of stressful events in the person's life in the past few months and the symptomatology associated with them. This interview is currently undergoing a validation process.

Self-reported questionnaires

Positive and Negative Affect Schedule-Trait (PANAS; Watson et al., 1988). The questionnaire consists of 20 items to assess a person's positive and negative affect as a trait on a 5-point scale (1= "very slightly or not at all"; 5="extremely"). Each of the two subscales includes 10 items. Both the original validation (Watson et al., 1988) and the Spanish validation (Sandín et al., 1999) showed two clearly differentiated factors (PA and NA) and good psychometric properties. In the current study, Cronbach's alpha was excellent for the PANAS-P (.91) and good for the PANAS-N (.87).

Beck Depression Inventory (BDI-II; Beck, Steer, & Brown, 1996), using the Spanish adaptation (Sanz, Navarro, & Vázquez, 2003). The questionnaire includes 21 items to assess the severity of depression, with four response alternatives ranging from 0 to 3. The instrument shows adequate internal consistency (Cronbach's alpha ranging from .76 to .96) and good test-retest

reliability (.8). The psychometric properties of the Spanish adaptation also show high internal consistency: Cronbach's alpha of .87 in the general population (Sanz, Perdigón, & Vázquez, 2003) and .89 in a clinical population (Sanz, García-Vera, Espinosa, Fortún, & Vázquez, 2005). Cronbach's alpha for the BDI-II in this study was excellent (.91).

Beck Anxiety Inventory (BAI); (Beck, Brown, Epstein, & Steer, 1988) using the Spanish adaptation (Sanz & Navarro, 2003). The questionnaire consists of 21 items assessing anxiety, with four response alternatives on a Likert scale. The Spanish adaptation showed high internal consistency ($\alpha = .93$) (Magán, Sanz, & García-Vera, 2008). In the present study, Cronbach's alpha for the BAI was excellent (.91).

Overall Anxiety Severity and Impairment Scale (OASIS); Norman et al., 2011). This questionnaire assesses the frequency and severity of anxiety with five items rated on a 0 to 4-point scale. The Cronbach's alpha for the scale was .80, and it showed good test-retest reliability ($k = 5, .82$). Cronbach's alpha for the OASIS in the current study was good (.87).

Patient Health Questionnaire-9 (PHQ-9); Kroenke, Spitzer, & Williams, 2001). This is a short questionnaire with 9 items (answers ranging from 0 to 3) that assess depressive symptomatology in the past two weeks. The questionnaire showed a Cronbach's alpha of .89, and test-retest reliability was also excellent (Kroenke et al., 2001). Cronbach's alpha for the PHQ-9 in this study was good (.85).

NEO-five factor Inventory (Costa & McCrae, 1992). The NEO FFI, abbreviated version of the NEO-PI-R, assesses five personality dimensions through 60 items rated on a Likert scale, with responses ranging from 0 to 4. In the present study, only the Neuroticism and Extraversion scales were used, with each scale containing 12 items. Internal consistency of the Extraversion subscale was .82, and .84 for the Neuroticism scale. Test-retest was .86 for Extraversion and .89 for Neuroticism. The Spanish version of the questionnaire also showed good properties (Aluja, García, Rossier, & García, 2005). In the present study, Cronbach's alpha was good for both the Neuroticism subscale (.80) and the Extraversion subscale (.86).

Treatments

Patients included in the study participated in different research projects based on self-applied online interventions conducted by the present research

group: Emotion Regulation, Adjustment Disorder Online (TAO), and Brief Online Protocols for Depression.

Emotion Regulation is a 12-module transdiagnostic web-based protocol for the treatment of depression and anxiety disorders. The protocol contains the following four core components adapted from the Unified Protocol (Barlow, Allen, & Choate, 2004) and from Marsha Linehan's protocol (Linehan, 1993): present-focused emotional awareness, cognitive flexibility, behavioral and emotional avoidance patterns, and interoceptive and situational exposure. The protocol also includes traditional therapeutic components of evidence-based treatments, such as psychoeducation, motivation for change, and relapse prevention (Díaz-García et al., 2017; González-Robles et al., 2015).

Adjustment Disorder Online (TAO) is a web-based protocol for the treatment of adjustment disorders. The protocol is organized in seven modules and comprises the following therapeutic components: psychoeducation, techniques to manage negative emotions, exposure, problem-solving techniques, mindfulness, acceptance and elaboration of the stressful event, positive psychology strategies, and relapse prevention. The TAO also includes behavioral activation for mood disturbance, problem-solving techniques, and a mindfulness component (Rachyla et al., 2018).

In the brief online depression protocols project, the depressed patients were randomly assigned to one of three Internet-based protocols: a) one based on a healthy lifestyle; b) another based on mindfulness; and c) the third one based on positive affect regulation. The main goal of the healthy lifestyle protocol is to learn that lifestyle habits (sedentary lifestyle, deteriorated sleep habits, spend most of the time indoors, etc.) play an important role in the course and treatment of depression. Bad habits make the symptoms worse, and it is important to learn how to change them. The main goal of the mindfulness protocol is to help patients become aware that we live in a society where it is common to perform various tasks simultaneously. This way of functioning, leads to high levels of inattention and distraction, which causes serious harm to our physical and mental health. Faced with this situation, mindfulness is an antidote because it helps us to realize the importance of our emotions and thoughts in our experience. Finally, the main goal of the positive affect regulation protocol is to teach the importance of: "moving on" to acquire a proper level of activity and involvement in life, being involved in pleasant and significant activities linked to

values and goals in life, and having contact with other people. Each protocol consists of four online modules.

All the treatment protocols are delivered through a multimedia web platform (<https://www.psicologiaytecnologia.com/>).

Data analysis

First, one-way ANOVAs were performed to analyze whether there were statistically significant differences in the scores on both subscales of the PANAS (PANAS-P and PANAS-N) based on gender, marital status, studies, principal diagnosis, and number of comorbid diagnoses. Correlations between age and the PANAS subscales were calculated to examine whether there were any associations between these variables. Additionally, reliability was analyzed by calculating both internal consistency (Cronbach's alpha) and test-retest reliability. These analyses were performed separately for the items of the PANAS-P and the PANAS-N. Temporal stability (test-retest reliability) of the PANAS-P and PANAS-N scores was assessed by calculating the Pearson correlation coefficient between the two measurement time points (pretest and posttest) of the control groups in the three studies. Pearson's r takes values on the interval $[-1,+1]$, quantifying the direction (+/-) and the strength of the relationship between test-retest scores by estimating their linear relationship (Vaz, Falkmer, Passmore, Parsons, & Andreou, 2013).

In order to analyze the latent structure of the PANAS, a Confirmatory Factor Analysis (CFA) was tested. CFA was used because the PANAS has previously been validated, and a theoretical structure of two correlated factors has repeatedly been found (DeVellis, 2006). WLSMV (Weighted Least Square Mean and Variance corrected) estimation was employed because the variables were not multivariate normal, and the items were categorical (i.e. Likert-type items). WLSMV is one of the best available estimation methods for this type of data (Caycho-Rodríguez, Ventura-León, García-Cadena, Tomás, Domínguez-Vergara, Daniel, & Arias-Gallegos, 2018; Finney & Di Stefano, 2013). Model fit was analyzed using several indices from different families, as recommended in the literature (Hoyle & Gottfredson, 2015; Tanaka, 1993). Specifically, all the indices and statistics available when WLSMV is used are presented: a) chi-square; b) Comparative Fit Index (CFI); Standardized Root Mean Residual (SRMR); and c) Root Mean Square Error of Approximation (RMSEA). Criteria for acceptable model fit were: CFI above .90 (better fit above .95) and RMSEA

and/or SRMR below .08 (Marsh, Hau, & Wen, 2004). The CFA was estimated with Mplus v.8 (Muthén & Muthén, 2017).

To examine construct validity, correlations between the PANAS-P and the PANAS-N and measures of anxiety (BAI, OASIS), depression (BDI-II, PHQ-9), and temperament (NEO-FFI) were calculated. Following Cohen's benchmarks (Cohen, 1988), correlation values were interpreted as follows: effect sizes between .10 and .30 were considered small, those between .30 and .50 were considered medium, and effect sizes of .50 or above were considered large. A negative but medium correlation between the PANAS-P and the PANAS-N was expected. A negative and medium correlation was expected between the PANAS-P and the anxiety (BAI, OASIS) and depression measures (BDI-II, PHQ-9). By contrast, a positive but medium correlation was expected between the PANAS-N and the anxiety and depression measures. Additionally, we hypothesized positive medium correlations between the PANAS-P and the NEO-FFI-E, and between the PANAS-N and the NEO-FFI-N. Finally, negative but medium correlations were expected between the PANAS-P and the NEO-FFI-N, and between the PANAS-N and the NEO-FFI-E. The theoretical foundation for this prediction was based on the commonalities shown between the constructs of affect and the personality dimensions of neuroticism and extraversion (Barlow, Sauer-Zavala, Carl, Bullis, & Ellard, 2014; Brown, & Barlow, 2009).

Finally, to analyze the sensitivity of the PANAS-P and PANAS-N scores to change, means and standard deviations for the pretest and posttest were calculated from three studies about the efficacy of Internet-based treatments in patients with anxiety and/or depressive disorders, adjustment disorders, and depressive disorders (Emotion Regulation, TAO, and the brief online protocols for depression groups). Study 1 consisted of 207 individuals who participated in a randomized controlled trial (RCT) comparing a transdiagnostic Internet-based protocol for emotional disorders to a waitlist control group (WLC) (136 patients allocated to treatment group and 71 to a WLC). Study 2 was an RCT with 39 participants that compared an Internet-based protocol for adjustment disorders to a WLC (16 allocated to treatment group and 19 to a WLC). Finally, study 3 comprised an RCT that compared brief online depression protocols to a WLC (105 participants from the treatment group and 20 from the WLC). For each study, minimum and maximum PANAS-P and PANAS-N scores were obtained from the treatment pretest and control groups to check for potential floor or ceiling effects. Evidence of floor or ceiling effects is present when more than 15%

of the participants obtain the lowest or highest possible score on the test, respectively (in our case, 10 and 50; cf. McHorney & Tarlov, 1995). In addition, for each study, *t*-tests were applied to test the statistical significance of the pretest-posttest mean differences of the treatment group. Furthermore, to quantify the sensitivity of the PANAS-P and PANAS-N scores to change, the standardized mean change index was used as the effect size, defined as the difference between the pretest and posttest means divided by the standard deviation of the change scores of the treatment group:

$$d = c(m) \bar{y}_{Pre} - \bar{y}_{Post} / SD_{Change}$$

with \bar{y}_{Pre} and \bar{y}_{Post} being the pretest and posttest means of a treatment group. The positive bias of the *d* index for small sample sizes was corrected with the *c(m)* correction factor:

$$c(m) = 1 - 3/(4N - 5)$$

In addition, 95% confidence intervals for the *d* indices were calculated by means of $d \pm 1.96 \times SE(d)$, with 1.96 being the 97.5 percentile of the standard normal distribution, and *SE(d)* being the standard error of the *d* index (Morris & DeShon, 2002):

$$SE(d) = \sqrt{c(m)^2 \times (1/n) \times (n - 1/n - 3) \times (1 + nd^2) - d^2}$$

All of these calculations were applied separately for studies 1 to 3. To offer a contextualized interpretation of the *d* indices, we used the results of a systematic review of meta-analyses on the efficacy of psychological treatments that applied the standardized mean change index as the effect size (Rubio-Aparicio et al., 2017). In this review, percentiles 25, 50, and 75 of the *d* indices' distribution were 0.64, 0.75, and 1.26. Therefore, a reasonable interpretation of these three values is to consider that they reflect low, moderate, and large magnitudes of the effect.

Results

Preliminary analyses

In the total sample, the mean PANAS-P score was 20.19 (SD = 6.91), and the mean PANAS-N score was 29.07 (SD = 8.14). Table 7-2 and

Table 7-3 show the means and standard deviations for each item and the total score on both the PANAS-P and the PANAS-N by diagnosis category.

On the PANAS-P, the results of one-way ANOVAs yielded statistically significant differences based on civil status, $F(3, 591) = 3.05, p < .05$, diagnostic category, $F(2, 592) = 12.22, p < .001$, principal diagnosis, $F(10, 584) = 5.56, p < .001$, and number of comorbid diagnoses, $F(3, 590) = 2.92, p < .05$. Sidak's post hoc tests showed that patients in the category of depressive disorders had significantly lower scores on PA than those in the categories of anxiety ($p < .001$) and adjustment disorders ($p < .05$). Additionally, the results of Sidak's post hoc tests showed that patients with MDD as the principal diagnosis had significantly lower scores on PA than patients with GAD ($p < .01$), AG ($p < .01$) and OCD ($p < .001$). On the PANAS-N, no significant differences were found on any of the sociodemographic or clinical variables, except for the number of comorbid diagnoses, $F(3, 590) = 9.07, p < .001$). Sidak's post hoc tests showed that patients with one or more comorbid disorders had significantly higher scores on NA, compared to patients with no comorbid diagnoses.

Table 7-2. Descriptive statistics for each item and the total score on the PANAS-P in patients with depression, anxiety, or adjustment disorder as principal diagnosis

	Depression (n = 237)		Anxiety (n = 284)		Adjustment disorder (n = 74)	
	M	SD	M	SD	M	SD
Item 1	2.24	.94	2.54	1.01	2.51	.98
Item 3	1.77	.85	2.19	.99	2.08	1.02
Item 5	1.80	.83	2.07	.92	1.93	.93
Item 9	1.56	.74	1.98	.89	1.89	.99
Item 10	1.74	.88	2.00	.94	2.00	.91
Item 12	2.00	.81	2.15	.87	2.11	1.00
Item 14	1.71	.81	1.94	.90	1.93	1.03
Item 16	1.78	.87	1.97	.93	2.14	1.09

Item 17	1.94	.86	2.05	.86	2.01	.99
Item 19	1.98	.90	2.30	.98	2.34	1.19
Total score	18.51	6.06	21.40	7.07	20.95	7.78

Table 7-3. Descriptive statistics for each item and the total score in the PANAS-N in patients with depression, anxiety, or adjustment disorder as principal diagnosis

	Depression (n = 238)		Anxiety (n = 284)		Adjustment disorder (n = 74)	
	M	SD	M	SD	M	SD
Item 2	3.47	1.04	3.61	1.06	3.68	1.09
Item 4	3.03	1.15	2.93	1.12	2.96	1.08
Item 6	2.87	1.39	2.63	1.27	2.78	1.39
Item 7	2.70	1.29	2.92	1.31	2.62	1.29
Item 8	2.28	1.08	2.19	1.09	2.36	1.14
Item 11	2.90	1.20	2.80	1.20	2.72	1.14
Item 13	2.24	1.27	2.41	1.32	2.32	1.32
Item 15	3.35	1.12	3.57	1.12	3.30	1.08
Item 18	3.28	1.12	3.43	1.11	3.24	1.02
Item 20	2.81	1.39	3.11	1.34	2.68	1.34
Total score	28.92	8.06	29.31	8.32	28.66	7.75

Reliability

Internal consistency

Cronbach's alpha was .91 for the PANAS-P and .87 for the PANAS-N. Table 7-4 and Table 7-5 display the outcomes for Cronbach's alpha when omitting items, corrected correlations between each item and the total score, and correlations between the items on the PANAS-P and the PANAS-N, respectively.

Table 7-4. Cronbach's alpha if item is deleted, corrected item-total score correlation, and correlations between items on the PANAS-P

		Correlations between items										
	Cronbach's alpha if item deleted	Corrected item-total correlation	1	3	5	9	10	12	14	16	17	19
1	.904	.717	1	.629	.600	.637	.463	.477	.533	.485	.477	.552
3	.904	.718		1	.591	.750	.520	.444	.529	.437	.403	.556
5	.902	.748			1	.658	.458	.595	.501	.498	.459	.681
9	.901	.777				1	.538	.498	.586	.501	.438	.596
10	.910	.606					1	.377	.492	.473	.382	.459
12	.908	.645						1	.445	.467	.510	.594
14	.907	.669							1	.528	.429	.515
16	.908	.643								1	.489	.524
17	.911	.593									1	.496
19	.903	.735										1

Note. All correlations were statistically significant at $p < .01$ (two-tailed)

Table 7-5. Cronbach's alpha if item is deleted, corrected item-total score correlations, and correlations between items for the PANAS-N

	Cronbach's alpha if item deleted	Corrected item-total correlation	Correlations between items									
			2	4	6	7	8	11	13	15	18	20
2	.858	.576	1	.467	.318	.339	.368	.471	.243	.588	.528	.305
4	.855	.607		1	.386	.354	.517	.612	.330	.391	.406	.317
6	.860	.554			1	.452	.363	.333	.536	.353	.359	.311
7	.852	.641				1	.308	.271	.428	.462	.461	.769
8	.860	.545					1	.660	.279	.322	.324	.273
11	.857	.574						1	.276	.398	.361	.259
13	.863	.517							1	.331	.317	.423
15	.853	.641								1	.686	.437
18	.853	.640									1	.504
20	.857	.591										1

Note. All correlations were statistically significant at $p < .01$ (two-tailed)

Test-retest reliability

For each of the three studies, test-retest reliability of the PANAS-P and PANAS-N scores was estimated by calculating the Pearson correlation coefficient between the two measurement times (pretest and posttest) of the control group. Table 7-6 presents the results. Although all of the test-retest coefficients were statistically significant ($p < .05$), it was evident that some of them were low, particularly, for the PANAS-P scores in Study 1 ($r = .261$).

Table 7-6. Test-retest reliability of PANAS-P and PANAS-N scores

Study	<i>N</i>	<i>r</i>	<i>p</i>
Study 1:			
PANAS-P	71	.261	.028
PANAS-N	71	.481	< .001
Study 2:			
PANAS-P	19	.525	.021
PANAS-N	19	.851	< .001
Study 3:			
PANAS-P	20	.621	.003
PANAS-N	20	.557	.011

Note. *N* = sample size of the control group for each study. *r* = test-retest reliability coefficient (Pearson correlation coefficient between pretest and posttest scores). *p* = probability level of the t-test for testing the statistical significance of test-retest coefficient.

Convergent and divergent validity

Table 7-7 shows the correlations between the PANAS-P and the PANAS-N and convergent and divergent validity measures. Significant correlations were found between both the PANAS-P and the PANAS-N and all the measures. As expected, a negative but medium correlation was found between the PANAS-P and the PANAS-N ($r = -.30, p < .01$). Negative and large correlations were found between the PANAS-P and depression measures (BDI-II: $r = -.56, p < .01$; PHQ-9: $r = -.52, p < .01$), whereas the correlations between the PANAS-P and anxiety measures were small to medium (BAI: $r = -.23, p < .01$; OASIS: $r = -.39, p < .01$). By contrast, positive large correlations were found between the PANAS-N and the depression (BDI-II: $r = .63, p < .01$; PHQ-9: $r = .54, p < .01$) and anxiety measures (BAI: $r = .58, p < .01$; OASIS: $r = .64, p < .01$). Finally, a negative but medium correlation was found between the PANAS-P and the NEO-FFI-N ($r = -.39, p < .01$), and a positive and medium correlation between the PANAS-P and the NEO-FFI-E ($r = .44, p < .01$). In addition, a positive and large correlation was found between the PANAS-N and the NEO-FFI-N ($r = .65, p < .01$), and a negative but small correlation was found between the PANAS-N and the NEO-FFI-E ($r = -.24, p < .01$).

Table 7-7. Correlations of the PANAS-P and the PANAS-N with convergent and divergent validity measures

	PANAS-P	PANAS-N	BDI-II	PHQ-9	BAI	OASIS	NEO-FFI-N	NEO-FFI-E
PANAS-P	1	-.30	-.56	-.52	-.23	-.39	-.39	.44
PANAS-N		1	.63	.54	.58	.64	.65	-.24
BDI-II			1	.83	.51	.66	.64	-.28
PHQ-9				1	.52	.63	.60	-.25
BAI					1	.63	.48	-.17
OASIS						1	.51	-.26
NEO-FFI-N							1	-.30
NEO-FFI-E								1

Note. All correlations were statistically significant at $p < .01$ (two-tailed). PANAS-P = Positive and Negative Affect Schedule - Positive Affect; PANAS-N = Positive and Negative Affect Schedule - Negative Affect; BDI-II = Beck Depression Inventory; PHQ-9 = Patient Health Questionnaire; BAI = Beck Anxiety Inventory; NEO-FFI-N = Neo Five-Factor Inventory - Neuroticism; NEO-FFI-E = NEO Five-Factor Inventory – Extraversion

Confirmatory Factor Analysis

The PANAS has a two-correlated factor structure, positive and negative affect. We have tested this two-factor structure with a CFA. The model reasonably fitted the observed data: $X^2(169) = 1425.31$, RMSEA = .112 CI [.106 - .117], CFI = .917, SRMR = .076. Fit was adequate according to both the CFI and the SRMR. RMSEA was a little higher than expected. However, and taking into account that the parameter estimates were all statistically significant and very large, we can conclude that the model fits adequately.

Table 7-8 shows a description of the items, their means and standard deviations, and the standardized factor loadings from the CFA. As mentioned above, all factor loadings were statistically significant ($p < .001$) and large. With regard to the first factor, all standardized loadings were in the range of .68 to .85. Regarding the second factor, again standardized loadings were large, with a minimum of .62 and a maximum of .83.

Table 7-8. Means, standard deviations, and standardized factor loadings

Item	Mean	SD	Factor 1	Factor 2
			Positive affect	Negative affect
1	2.42	0.98	0.79	
2	3.56	1.04		.67
3	2.01	0.96	.85	
4	2.97	1.12		.70
5	1.95	0.89	.85	
6	2.75	1.33		.62
7	2.79	1.30		.83
8	2.25	1.09		.70
9	1.80	0.87	.89	
10	1.90	0.91	.71	
11	2.83	1.19		.75
12	2.09	0.86	.73	
13	2.33	1.29		.59
14	1.85	0.88	.74	
15	3.45	1.11		.75
16	1.92	0.93	.73	
17	2.00	0.87	.68	
18	3.35	1.10		.75
19	2.18	0.98	.81	
20	2.94	1.36		.80

Sensitivity to change

To examine potential floor and ceiling effects for the PANAS-P and PANAS-N scores, the frequency and percentage of minimum (10) and maximum (50) scores on the pretest were tabulated for each study, using the participants in the treatment and control groups. As Table 7-9 shows, floor and ceiling effects

can be ruled out because, the percentage of minimum and maximum scores was less than 15% in all three studies.

Table 7-9. Frequency (and %) of minimum (10) and maximum (50) scores on the pretest in the three studies

Study	<i>N</i>	Minimum (10)	Maximum (50)
Study 1:			
PANAS-P	207	4(1.9%)	0(0%)
PANAS-N	207	0(0%)	1(0.5%)
Study 2:			
PANAS-P	35	2(5.7%)	0(0%)
PANAS-N	35	0(0%)	0(0%)
Study 3:			
PANAS-P	125	4(3.2%)	0(0%)
PANAS-N	125	0(0%)	0(0%)

In addition, means and standard deviations of the pretest and posttest were calculated for the treatment groups in each study. The statistical significance of the pretest-posttest change scores was assessed by applying *t*-tests. As

Table 7-10 shows, statistically significant pretest-posttest differences were found in the three studies, for both PANAS-P and PANAS-N scores. The clinical significance was assessed by means of the effect size index 'standardized mean change index' (d). Following Rubio-Aparicio et al.'s (2017) results, with the exception of the PANAS-P scores in Study 3, all effect sizes were of moderate to large magnitude (all over 0.74).

Table 7-10. Descriptive and inferential results for the PANAS-P and PANAS-N scores on the pretest and posttest of the treatment groups in the three studies

Study	N	Pretest		Posttest		t	d[95%CI]
		Mean	SD	Mean	SD		
Study 1:							
PANAS-P	136	20.51	6.90	26.42	9.10	8.62***	0.74[0.54; 0.93]
PANAS-N	136	31.24	8.17	21.01	8.28	14.20***	1.21[0.99; 1.43]
Study 2:							
PANAS-P	16	20.00	8.97	32.00	8.45	5.74***	1.36[0.63; 2.09]
PANAS-N	16	30.44	8.14	20.69	6.60	4.21***	1.00[0.37; 1.63]
Study 3:							
PANAS-P	105	19.12	6.16	23.64	8.45	6.32***	0.61[0.40; 0.82]
PANAS-N	105	27.99	8.47	21.75	8.65	8.04***	0.78[0.56; 1.00]

Note. N = sample size. SD = standard deviation. t = t statistic for testing the pretest-posttest mean difference. *** p < .001. d = standardized mean change index (95%CI in brackets)

Discussion

The present study was designed to evaluate the psychometric properties of the PANAS scale in a Spanish clinical sample of patients with anxiety, depressive, and adjustment disorders. In addition, its objective was to contribute to the importance of evidence-based assessment by validating the scale applied in an online format. At the same time, the current study investigated the factorial validity of the Spanish version of the PANAS using exploratory and confirmatory factor analyses.

Preliminary analyses showed that, regarding sociodemographic data, no statistically significant differences were found based on gender, education level, or marital status. By contrast, regarding the clinical data, statistically significant differences were found depending on the principal diagnosis, showing that patients with depression had lower levels of PA than patients with anxiety and adjustment disorders. No differences were found in NA based on the principal diagnosis. These results are consistent with the literature, indicating that low levels of PA predict the onset of depression (Snyder & Lopez, 2009), dampen positive emotions, and increase the severity of the problem (Gilbert, Nolen-

Hoeksema, & Gruber, 2013). In fact, the literature shows that depressive symptoms often involve low levels of positive emotions, and that low levels of positive affect are more strongly linked to depression than to other emotional disorders (Barlow, Allen & Choate, 2004; Brown & Barlow, 2009; Watson & Naragon-Gainey, 2010).

Furthermore, taking into account the number of comorbid disorders, 35% of the sample presented at least one comorbid anxiety or depressive disorder. The results show that patients with more comorbid diagnoses had significantly higher NA and lower PA than patients with fewer comorbid disorders, which coincides with the evidence showing that severity is strongly related to comorbidity (Kessler, Chiu, Demler, Merikangas, & Walters, 2005). Regarding reliability, it is generally accepted that alpha coefficients must be over .70 for exploratory research, over .80 for general research purposes, and over .90 when the test is used for making clinical decisions (Nunnally & Bernstein, 1994). In addition, Cicchetti (1994) suggested the following guidelines for assessing the clinical relevance of alpha coefficients: unacceptable for coefficients lower than .7, fair for the .7 - .8 range, good for the .8 - .9 range, and excellent for values over .9. Therefore, according to these criteria, both the PANAS-P and the PANAS-N exhibited good to excellent internal consistency reliability (alphas of .91 and .87, respectively).

Regarding reliability as temporal stability, there is no consensus in the literature about guidelines for interpreting test-retest coefficients (Charter, 2003). Using the benchmarks mentioned above for internal consistency, we can conclude that the test-retest reliability in Study 1 was very low for both for the PANAS-P and PANAS-N scores ($r = .261$ and $.481$, respectively). In Study 2, test-retest reliability was low for the PANAS-P scores and good for the PANAS-N scores ($r = .525$ and $.851$, respectively). In Study 3, test-retest reliability was poor for both the PANAS-P and PANAS-N scores ($r = .621$ and $.557$, respectively). An explanation of the low test-retest reliability found in Study 1 could be the long time interval between the two measurement times (pretest-posttest), 16 weeks, in comparison with Studies 2 and 3: 7 and 4 weeks, respectively. Test-retest reliability seems to be an important type of reliability within the psychometric literature on online psychological programs, given that numerous factors (e.g. changes in test-taking attitudes) can vary online performance and the subsequent results (Buchanan & Smith, 1999). In this vein, it is important to highlight that participants in the control condition were offered the possibility of

receiving the treatment protocol after the wait time of 16 weeks, which may have had an influence on the results.

Regarding construct validity, convergent and divergent validity were demonstrated by correlations between the PANAS-P and PANAS-N and the depression, anxiety, and personality measures. Overall, significant correlations were found between positive and negative affect and all the measures. Convergent and discriminant validity were supported because NA scores were strongly correlated with symptoms of depression (measured by the BDI-II and PHQ-9) and anxiety (measured by the BAI and OASIS), whereas PA showed strong inverse correlations with depression measures and small to medium correlations with anxiety measures. Finally, as expected, the PANAS-P correlated significantly with the NEO-FFI-E and negatively with the NEO-FFI-N. At the same time, the PANAS-N correlated significantly with the NEO-FFI-N, and inversely with the NEO-FFI-E. Although the small correlation found between the PANAS-N and the NEO-FFI-E might stand out, this result is theoretically expected due to the commonalities shown between the affectivity and temperament dimensions of neuroticism and extraversion. The presence of high levels of neuroticism has been related to experiences of NA, whereas PA has traditionally been more related to the extraversion dimension (Barlow, Sauer-Zavala, Carl, Bullis, & Ellard, 2014; Brown & Barlow, 2009).

This study also examined the latent structure of the PANAS, and Confirmatory Factor Analysis was performed. The confirmatory factor analysis yielded a latent structure of two independent factors, coinciding with previous validations of the instrument and with the theoretical framework of positive and negative affect that conceptualizes them as two independent temperamental dimensions (Bradburn, 1969; Watson & Tellegen, 1985; Watson & Clark, 1992).

Regarding sensitivity to change, this study also analyzed the significance of the improvements from pre- to post-treatment on the PANAS scores. The results showed statistically significant pretest-posttest differences in the three studies, for both PANAS-P and PANAS-N, with moderate to large effect sizes, suggesting that the scale is able to detect changes in affectivity and, therefore, can be used to examine the impact of an intervention.

Overall, the results obtained in this study show adequate psychometric properties for the online version of the PANAS as a measure for the assessment of positive and negative affect in a Spanish clinical population. These results

reinforce the importance of validating online assessment instruments, given the current proliferation of Internet-based psychological treatments.

The present study has several strengths. First, to our knowledge, this is the first study to evaluate the psychometric properties of the PANAS in a Spanish clinical population. Second, this is the first validation of this instrument in an online format. The literature presents considerable evidence about the efficacy of Internet-based interventions for emotional disorders (Andersson & Cuijpers, 2009; Andrews, Cuijpers, Craske, McEvoy & Titov, 2010). Recently in our country, studies have been carried out that also guarantee their efficacy (Mira et al., 2017; Montero-Marín et al., 2016; Romero-Sanchiz, 2017), and so it is important to have validated online assessment tools that can be used to assess PA and NA (two core symptoms) in research and clinical settings. In this vein, the present study provides empirical evidence about the usefulness of the instrument in distinguishing between PA and NA using a digital version of the questionnaire. Furthermore, online assessment also has advantages in clinical practice and routine care, where there are always time limitations. In this way, it is possible to reach more people in less time than with paper and pencil evaluations. Research results encourage the online use of questionnaires because they offer many advantages over traditional data collection methods (Carlbring et al. 2007; Hedman et al. 2010; Vallejo et al. 2007). For instance, missing data can be handled in a more straightforward way, and scoring is easy and immediate (Carlbring et al. 2007). In addition, online assessment allows users to receive feedback about their progress (Barak and English 2002). Finally, the high diagnostic heterogeneity in the present study (i.e. individuals with anxiety, depressive, and adjustment disorders) helps to increase the generalizability of the results.

This study has several limitations that should be mentioned. First, it was not possible to calculate sensitivity to change with the whole sample because post-treatment scores were not available for all the participants in this study. Second, the validation was limited to participants with psychological disorders. Therefore, we were not able to obtain cutoff scores for the PANAS.

In conclusion, the results of this study support the adequacy of the PANAS applied online in Spanish clinical samples suffering from different mental disorders (i.e. anxious, depressive, and adjustment disorders). All in all, the present study provides a psychometrically-validated online measure to assess the structure of affect and supports the application of the PANAS in clinical

settings. This online validation can have a direct impact on evidence-based assessment, facilitating access to appropriate instruments for evaluating affectivity in mental disorders.

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Chapter 8: General discussion

General discussion

It is widely known that ED have an enormous impact on mental health, disrupting the lives of millions of people each year and being the main cause of disability worldwide (McLean et al., 2011). Numerous EBTs have been developed to directly address the great worldwide treatment needs (Kazdin, 2015). However, these interventions do not reach everyone in need (Bebbington et al., 2000). Given this situation, new proposals based on the transdiagnostic perspective have emerged, with the objective of simultaneously treating more than one disorder (e.g. anxiety and depression, or multiple anxiety disorders) and improving treatment efficiency. In addition, the accumulating data about the potential benefits of using strategies to promote positive emotions to up-regulate PA have been pointed out, and the focus has been on incorporating positive psychological components into treatments (Ehrenreich et al., 2007). The aims of the present thesis were as follows: 1) to test the feasibility of including a component focused on up-regulating PA in a psychological treatment for people suffering from depressive symptoms; 2) to examine the studies that have been carried out in the field of psychological interventions to promote resilience, in terms of the efficacy and methodological and theoretical adequacy of these interventions; 3) to test the efficacy of a transdiagnostic Internet-based treatment for ED that includes traditional cognitive-behavioral therapy components, as well as a specific component to address positive affect, versus a waiting list control group; 4) to analyze the subjective experience of a sample of patients who dropped out of a transdiagnostic IBT for ED; and 5) to investigate the psychometric properties of the online Spanish version of the Positive and Negative Affect Schedule (PANAS) in a clinical sample of individuals with ED. The research questions posed in the introduction will be summarized in this discussion section, along with a general discussion of important conclusions that emerge from all the studies.

Key findings

- **Which is the feasibility of a positive clinical psychology intervention for depressive symptoms?**

Before adapting the transdiagnostic protocol to a multimedia web platform in order to apply it over the Internet, a feasibility study was conducted to explore the effect of the protocol on depression, anxiety, positive, and negative affect (Chapter 2). Results showed that the intervention was feasible, not only for

reducing depression, anxiety and negative affect, but also for increasing positive affect and orientation towards enjoyment. In addition, regarding the opinion of the participants, the protocol was well-accepted, and participants said they were very satisfied with the treatment, found it very logical and useful even for other psychological problems, and would recommend it to a friend. With this study, the feasibility of a manualized positive clinical psychology protocol was tested, supporting the idea of adapting it to a web platform to reach more people in need. The protocol included components of evidence-based treatments and a positive psychology component, offering strategies to promote and enhance personal strengths, positive feelings, positive cognitions, and positive behavior (Seligman & Csikszentmihalyi, 2000; Sin & Lyubomirsky, 2009). The positive results in this study supported the development of interventions with a focus on both negative and positive aspects of human functioning to achieve a more comprehensive psychotherapy (Rashid, 2009).

- **What is the effectiveness of Internet-based training interventions in improving PA and resilience?**

A meta-analysis was conducted that synthesized studies that focused on Internet-based training interventions for improving resilience, positive emotions, and quality of life, in terms of efficacy, theoretical adequacy, and methodological quality (Chapter 3). Results showed that overall effects of resilience training compared to a control group at post-test were not significant. However, a benefit was found in the studies with a clear assessment theory, indicating that there might be some promising effects. These findings provided important information about the enormous need to clarify the concept of resilience, design studies with better methodologies, and conduct more research on the effectiveness of these intervention programs in promoting PA. In this light, an Internet-based transdiagnostic treatment with a specific component to address PA was designed and tested in a community sample of people with ED.

- **Is a transdiagnostic Internet-based intervention with a specific component to the effectiveness of PA in treating ED, in terms of depressive and anxious symptomatology and improving PA (up-regulating PA)?,**

One of the main objectives of this doctoral dissertation was to analyze in a randomized controlled study, the efficacy of a transdiagnostic Internet-based treatment for ED in a community sample (Chapters 4 and 5).

The protocol includes traditional Cognitive Behavioral Therapy components for down-regulating NA (Transdiagnostic Internet-based Protocol –TIBP–), as well as a specific component to address PA (Transdiagnostic Internet-based Protocol + Positive Affect Component –TIBP + PA–), and it was adapted for application online over the Internet, which can help to achieve a successful dissemination of transdiagnostic treatment protocols and reach everyone in need. Furthermore, the specific objectives were: a) to test the efficacy of both treatment modalities on depressive and anxious symptomatology, as well as their possible impact on basic personality dimensions (i.e neuroticism and extraversion); b) to assess the differential efficacy of the transdiagnostic treatment with the specific component to up-regulate PA; and c) to analyze the acceptance of the Internet-based program with minimal support by the clinician in terms of expectations, satisfaction, and opinions. Taking into account the objectives set out above, the hypotheses tested were as follows:

H1. Both self-applied protocol modalities (TIBP and TIBP + PA) will be more effective than the waiting list control condition in the treatment of ED.

H2. Both interventions will result in significant improvements in depressive and anxious symptomatology at post-treatment.

H3. The TIBP + PA will significantly outperform the TIBP group on PA measures.

H4. Both protocols will be well accepted.

Supporting the hypotheses proposed, the results of the study showed the efficacy of the online transdiagnostic treatment (with and without the specific component to up-regulate PA) for the treatment of ED, compared to the waiting list control group. As predicted, both self-applied protocol modalities (TIBP and TIBP + PA) led to significantly greater reductions (compared to the waiting-list control group) in depressive and anxious symptomatology, as well as significant increases in PA measures. In addition, the treatment showed significant change from pre to post treatment on personality and quality of life measures, with participants experiencing low levels of neuroticism and high levels of extraversion and quality of life. Regarding PA measures, it is important to highlight that within-group comparison indicated significant pre-post reductions with large effect sizes on the PANAS+ in the TIBP + PA condition, whereas the TIBP condition obtained medium effect sizes on the same measure. The positive results from this randomized controlled trial offer a more solid base for the assumption that

positive affect components to up-regulate PA should be as essential as traditional CBT components to down-regulate NA in psychological interventions. Nonetheless, caution must be used because, when comparing the two interventions, the TIBP + PA condition did not outperform the TIBP condition on PA measures. Although small effect sizes were found between the two intervention groups on PA measures, there was not enough statistical power to detect significant differences between the two conditions. In this regard, it is important to point out that participants receive the specific component to up-regulate PA after having received the traditional ones, which can lead to a carryover effect of all the aspects and components worked on in the previous modules, thus improving PA measures in both intervention conditions (e.g. behavioral activation strategies such as recommending activities or setting meaningful goals from the first modules). There is theoretical and empirical evidence suggesting that PA and NA are relatively independent (Vazquez, Hervás, & Ho, 2006; Keyes & Waterman, 2003). Therefore, clinical symptoms experienced by a person can be effectively reduced with traditional CBT components, but this does not necessarily lead to a significant improvement in their lives. It is essential to continue working on the development of intervention protocols that, like the one presented in this thesis, are focused on diminishing NA as well as increasing PA. Future research should test, in an adequately powered sample, the differential effect of adding a specific therapeutic component to up-regulate PA. However, to the best of our knowledge, this is the first study of a transdiagnostic Internet-based treatment for ED with a specific component to up-regulate positive affectivity.

In this study, the Internet has been shown to be an effective tool for delivering a transdiagnostic treatment for ED that includes images, vignettes, vides, etc., in a multimedia web platform developed for optimal use on a PC or a tablet. In addition, participants rated the online program positively and showed good acceptance, with both protocols being well-accepted. However, the analysis revealed that, before and after treatment, participants in the TIBP + PA condition reported feeling more satisfied with the treatment, would recommend it to a friend, and considered the treatment more useful for other psychological problems than the participants in the TIBP condition. These results suggest the need to address user preferences as a way to improve interventions and possibly increase adherence and effectiveness (Tarrier, Liversidge, & Gregg, 2006; Soucy & Hadjistavropoulos, 2017). In addition, another important consideration is the

need to educate patients about self-administered treatments through the Internet (Soucy, Owens, Hadjistavropoulos, Dirkse, & Dear, 2016), making them aware of how self-administered interventions work and how they can be effective with automated support.

Overall, the findings represent an important advance in the field of ED and add evidence for the efficacy of an Internet-based treatment based on the transdiagnostic perspective. This study aims to contribute to the literature on the efficacy of transdiagnostic approaches to emotional disorders in general, and it more specifically explores the impact of a specific component designed to up-regulate PA.

- **What are the potential barriers of such transdiagnostic Internet-based treatments?**

In Chapter 6, a qualitative analysis of the subjective experience of a sample of patients who dropped out of a transdiagnostic IBT for ED was conducted. In this chapter, the potential barriers to the implementation of these interventions were discussed. The results showed that participants put a great emphasis on the lack of individualization, associated with the content received during the treatment, which may not target the specific problems, and the lack of supportiveness, related to the lack of affective and personal contact with the therapist. A more tailored management of expectations as well as strategies to enhance the therapeutic relationship in certain clients were identified as the two key elements in improving the dropout rate in IBTs. In addition, incorporating already developed lines on user-centered designs (De Vito Dabbs et al., 2009), person-based approaches (Yardley, Morrison, Bradbury, & Muller, 2015), or practice-oriented research (Castonguay, Barkham, Lutz, & Mcleavey, 2013) seemed to be essential. This study makes it possible to better grasp the phenomenon of dropout in IBTs and delineate specific implications in terms of research, training, and practice.

- **Is the PANAS a reliable measurement of PA in a Spanish clinical sample of patients with anxiety, depressive, and adjustment disorders to be included as a primary outcome of PA in the RCT?**

The proliferation of Internet-based treatments has led to the development of a wide range of assessments conducted online, using digital versions of pen and paper self-report questionnaires (Alfonsson, Maathz, & Hursti, 2014; Seib-Pfeifer, Pugnaghi, Beauducel, & Leue, 2017). In this vein, the PANAS has been used in

numerous Internet-based interventions (Botella et al., 2016; Mira et al., 2017). However, the psychometric properties of the scale had not yet been examined in clinical samples with patients suffering from anxiety, depression, or adjustment disorders. The PANAS was included in our RCT about the efficacy of an Internet-based treatment for ED as one of the primary outcomes. Therefore, we investigated the psychometric properties of the online Spanish version of the PANAS in a clinical sample in order to determine the factor structure of the scale, assess its construct validity, examine the scale's internal consistency and test-retest reliability, and analyze sensitivity to change (Chapter 7). The results showed adequate psychometric properties for the online version of the PANAS as a measure for the assessment of positive and negative affect in a Spanish clinical population. In addition, to the best of our knowledge, this is the first study to evaluate the psychometric properties of the PANAS in Spanish clinical samples in an online format. This study contributes to emphasizing the importance of validating online assessment tools that can be used for the assessment of PA and NA in research and clinical settings, facilitating access to appropriate instruments for evaluating affectivity in mental disorders.

Strengths and limitations

This dissertation includes the results of a series of studies that should be interpreted in light of their strengths and limitations. The general and most relevant limitations that must be taken into account when interpreting the results are presented in this section.

First, the feasibility study about a positive psychology intervention that includes a specific component to up-regulate PA was tested in patients with depressive disorder (Chapter 2). Although this intervention was shown to be feasible, it was developed in a face-to-face format. Before adapting the protocol to a web platform to be applied over the Internet, a feasibility study in an online format would have been more appropriate to draw firmer conclusions.

Second, in the meta-analysis of Internet-based training interventions for improving resilience, positive emotions, and quality of life (Chapter 3), only psychological interventions focusing on resilience in their rationale or design and applied over the Internet were included. However, there is little consensus about the fundamental components for a program to be considered a resiliency intervention, and even less, applied online. Therefore, the inclusion process in

this study was too restrictive and could be an obstacle to drawing conclusions with a high level of reliability.

Third, in the RCT of a transdiagnostic Internet-based treatment for ED with a specific component to up-regulate positive affectivity, high attrition rates were found (Chapter 4). Although the study expected dropout rates of around 30%, based on the literature (Andrews, Cuijpers, Craske, McEvoy, & Titov, 2010; Van Ballegooijen et al., 2014), a 37% dropout rate was obtained at the end of the program. This aspect seems to be a regular and natural feature of online intervention trials (Eysenbach, 2005). However, in order to prevent bias in the results, intention-to-treat analyses were conducted. In addition, although small effect sizes were found between the two intervention groups on the PA measures, there was not enough statistical power to detect significant differences between the two conditions. Therefore, future research should test, in an adequately powered sample, the differential effect of adding a specific therapeutic component to up-regulate PA.

Fourth, in the qualitative study about the experiences of patients who dropped out of the transdiagnostic Internet-based treatment, one of the major limitations was the retrospective recollection of experiences that were subject to strong biases depending on the participant's awareness of the past event (Chapter 5). Nevertheless, this limitation is shared by most qualitative studies as one of the methodological limitations. The key feature for qualitative research is data saturation, which means that data collection should be pursued until no new conceptual insights are generated. In this study, the last analyzed interview did not produce an increase in the number of domains, and so no more interviews were conducted.

Fifth, in the study of the psychometric properties of the PANAS (Chapter 6), it was not possible to calculate sensitivity to change with the whole sample due to the fact that scores at post-treatment were not available for all the participants in this study. Furthermore, the validation was limited to participants with psychological disorders. Therefore, we were not able to obtain cutoff scores for the PANAS. Nonetheless, the study supported the adequacy of the PANAS applied online in Spanish clinical samples suffering from different mental disorders.

Despite the limitations, the studies presented in this thesis also display some important strengths. In this dissertation, one of the main objectives was to

make progress in resolving some of the challenges in the field of mental health, specifically in understanding the necessary treatment components to improve the efficacy of psychological treatments and strengthen people's resilience, making them less vulnerable (Collins et al., 2011). The transdiagnostic perspective provides an explanation for the high rates of comorbidity observed in clinical practice and a worthwhile option to simultaneously treat more than one disorder with a single protocol (Clark & Taylor, 2009). In addition, PA has increasingly been taking on a fundamental role as a treatment component in psychological interventions (Bolier et al., 2013). In addition to this, technology offers an important opportunity to facilitate the availability of EBTs (Kazdin & Blase, 2011; Kazdin, 2015), and it can be used for both the assessment and treatment of clinical conditions (Andersson, 2015). In this regard, as Riva (2012) pointed out, it is possible to combine objectives of positive psychology with enhancements from technologies, resulting in "Positive Technology", with the main aim of using technology to enhance wellbeing or generate strengths and resilience (Riva et al., 2012; Botella et al., 2012). Combining a transdiagnostic approach with an online therapy format and adding the specific PA component may help to achieve a clear impact on the design and application of future transdiagnostic treatment protocols for ED, as a way to more effectively address the temperament vulnerabilities, that is, the core aspects of these disorders. This may be identified as the first major strength of this thesis because this is the first RCT of a transdiagnostic Internet-based treatment for ED with a specific component to up-regulate positive affectivity.

The quality of the study design can also be considered a strength of the RCT about the Internet-based treatment for ED with a specific component to up-regulate PA. Quality standards for conducting RCTs based on Cochrane criteria were applied, such as registering the clinical trial and publishing the research protocols beforehand (Chapter 4).

Another strength of the thesis is that in the meta-analysis of online interventions targeting resilience, only RCTs were included. Although the level of quality of the interventions was assured, the overall effect of resilience training was not significant. In this meta-analysis, the studies with a solid assessment theory had better overall effects than studies with an unclear assessment theory, possibly because of a close match between what the intervention was supposed to improve and what the study actually measured.

An additional strength of this thesis is that a qualitative study examining clients' experiences from a qualitative perspective is included in this compendium. To date, the most common approach used in the research on IBT dropout has been based on quantitative methodologies, and few studies have posed the question about the experience of dropping out of an IBT.

Finally, the inclusion of the first study to evaluate the psychometric properties of the PANAS in Spanish clinical samples in an online format can also be considered as a strength of the present thesis. This study contributes to the importance of evidence-based assessment (Hunsley & Mash, 2007).

Considerations and future recommendations

This thesis includes a series of studies that yield useful insights on the research questions posed in the general introduction. Despite the limitations, there are several strengths that lead to a series of interesting questions to be addressed in the future, consolidating or opening future lines of research.

In this section of the thesis, different aspects will be addressed in order to strengthen the research field on the impact of positive psychological interventions applied online from a transdiagnostic perspective.

Dropout rates

As the results presented in the RCT (Chapter 5) show, there were high attrition rates in the trial, especially in the intervention groups. Although high dropout rates were expected and are considered a natural feature of online trials (Eysenbach, 2005), future research is required to combat these high percentages, perhaps including specific strategies or studying the characteristics of dropouts to identify dropout predictors and risk groups. The inclusion of persuasive technologies and automated support are presented as useful tools for this purpose (Kelders, Kok, Ossebaard, & Van Gemert-Pijnen, 2012). The online transdiagnostic protocol tested in our RCT contained persuasive elements such as weekly mobile phone text messages, multiple-choice questions about the contents seen in each module, and automatic emails with reminders to access the program when participants have not entered in the past 15 days. However, the intervention could have been more personalized and tailored to users' preferences and needs. Future research should focus on increasing engagement and completion rates. Despite the high attrition rates, the online transdiagnostic intervention with a specific component to up-regulate PA significantly enhanced the PA of participants.

Dissemination and Implementation

It is essential to disseminate empirically supported psychological interventions, and the use of technology and the Internet can aid in this endeavor (Fairburn & Patel, 2017). Educating patients and clinicians about the potential benefits of Internet-based treatments, increasing their understanding about how they work and how to access them, seems to be a fundamental way to make progress in the dissemination of interventions through the Internet, improving access to EBTs. According to Soucy and Hadjistavropoulos (2017), further methods are needed to improve people's perception of online interventions. Furthermore, the implementation of EBTs has become increasingly important, as well as the quality of the implementation. The evidence from EBTs has typically been obtained under controlled conditions with RCTs. However, less is known about the extent to which treatment outcomes can be maintained in routine clinical practice (Bales et al., 2017). Further research is needed to better understand the barriers and facilitators in the implementation and maintenance of EBTs. These aspects are also relevant for interventions that use technology to improve wellbeing (i.e. Positive Technology (Riva et al., 2012; Botella, 2012). Future steps should be, for example, to apply the online transdiagnostic treatment for ED with the specific component to up-regulate PA tested in this thesis in other settings, such as primary care.

Research and clinical practice

An important issue is the transfer of results from the research context to a clinical practice context. Over the years, a substantial gap between these two fields have been pointed out, known as the research-practice gap or evidence-practice gap (Lilienfeld et al., 2013). For this reason, it is crucial that efforts be made to make interventions available that have been shown to be effective in RCTs. An integration of theory, practice, and research is most likely to optimize the effectiveness of psychotherapy (Fernández-Alvarez, Gómez, & García, 2015).

Transdiagnostic perspective

Transdiagnostic treatments have emerged in order to emphasize the essential processes underlying different disorders. These treatments address various psychological disorders with one single protocol (Clark & Taylor, 2009), and they have several advantages in comparison with disorder-specific treatments protocols. First, these disorders can be treated in a more cost-

effective way because clinicians only have to be trained in one protocol instead of different protocols for each specific diagnosis. Second, the dissemination of EBTs can be facilitated with transdiagnostic treatments (Barlow, Allen & Choate, 2004), especially in ecological settings such as public mental health services, where the adequate selection of protocols and techniques may be difficult (Sauer-Zavala et al., 2016). Finally, another important advantage is that comorbid mental disorders can be more adequately targeted with transdiagnostic treatments because they focus on the common biological and psychological vulnerabilities (Barlow, 2004; Barlow, 2013). Given the substantial evidence of the efficacy of transdiagnostic treatments (Norton, 2008; Norton, Hayes, & Hope, 2004; Titov, Andrews, Johnston, Robinson, & Spence, 2010; Carlbring et al., 2011; Dear et al., 2011; Titov et al., 2011; Farchione et al., 2012; Newby et al., 2015), future research should focus on the integration of a personalized, modular approach with a mechanistically transdiagnostic intervention (i.e. personalizing the treatment to a specific presentation by selecting the treatment components that best fit the specific set of symptoms shown by each patient) (Sauer-Zavala, Cassiello-Robbins, Ametaj, Wilner, & Pagan, 2018).

PA components in psychological interventions

Extensive evidence shows that PA has correlations with a range of health and health-relevant outcomes, with PA being uniquely valuable due to the potential to help people live longer, healthier, and higher-quality lives (Pressman, Jenkins, & Moskowitz, 2018).

The RCT included in this thesis aimed to explore the effect of treatment components on increasing wellbeing and PA. The positive results obtained offer evidence that components targeting PA are essential in psychological interventions as one of the future routine components of evidence-based psychological treatments. Providing interventions focused on up-regulating PA may offer opportunities to develop protective factors and enhance personal strengths, positive feelings, positive cognitions, and positive behavior (Sin & Lyubomirsky, 2009). Literature has highlighted that interventions that include PA components can be effective in the enhancement of subjective well-being and psychological well-being, as well as in reducing depressive symptoms (Bolier et al., 2013). PA components can engage and empower participants to take charge of their own health through strategies and tools that promote well-being (Bolier & Abello, 2014).

Further research would be required to continue to develop and test treatment components focused on enhancing protective factors and resilience and mitigating risk factors. However, evidence suggests that the most complete form of positive interventions is one that integrates aspects relating to wellbeing and health (aimed at up-regulating PA) with aspects that are already included in most psychological treatments, focused on deficits (aimed to down-regulating NA) (Vázquez & Hervás, 2008).

Digital interventions

The extensive use of ICTs has gradually changed people's lives. The use of laptops, smartphones, tablets, and other personal devices has become increasingly widespread in the past few decades, and digital interventions have also found a place within mental healthcare systems (Fairburn & Patel, 2017). Psychological treatments for mental health problems can be applied over the Internet or through mobile software applications (apps), with the advantages of doing the treatment from home, at one's own pace, and at convenient times. Furthermore, several innovations to better understand psychological states have been developed in the past few decades, as in the case of sensors embedded in mobile phones to measure physical properties and information related to behaviors, thoughts, emotions, and clinical states and disorders (Mohr, Zhang, & Schueller, 2017). In addition, smartphones can collect an enormous amount of ecologically valid data easily and quickly from large global samples, which can revolutionize current psychological interventions (Miller, 2012). On the other hand, virtual reality has also emerged to improve psychological treatments, with enormous potential for both research and clinical practice (e.g. the use of digital representation (avatar) to receive therapy) (Craig et al., 2018). It is not surprising, therefore, that technological advances promise to be highly beneficial in assessing and treating clinical conditions. Both digital assessments and treatments are emerging, and the potential of this burgeoning area is also related to positive psychological interventions.

To conclude this section, future developments and research on online transdiagnostic treatments should focus on carrying out strategies to reduce dropout rates in IBTs, considering dissemination and implementation as a fundamental factor, incorporating PA components to directly up-regulate PA, and exploring digital interventions to reach everyone in need of a psychological treatment.

Conclusion

The studies included in this thesis contribute to the field of transdiagnostic treatments applied over the Internet and, in particular, to positive psychological interventions addressing not only NA but also PA. An online transdiagnostic treatment for ED has been shown to be effective in improving clinical symptomatology, both with the specific component to up-regulate PA and without it, observing significantly higher improvements in both intervention groups compared to the non-intervention group (WL control group). Special emphasis has been placed on exploring the available evidence about the effectiveness of Internet-based training interventions to improve resilience, with the aim of clarifying the field and developing new interventions focused on promoting PA. In addition, the experiences of patients who drop out of a transdiagnostic Internet-based treatment have been taken into account, which allows more profound and comprehensive knowledge about the phenomenon of dropout in IBTs from a qualitative perspective. Finally, as a complement to the rest of the studies, the focus has been placed on evidence-based assessments, testing the psychometric properties of the PANAS.

This thesis is framed within the positive psychological research and transdiagnostic approaches, trying to contribute to the efficacy of these interventions and make evidence-based online treatments widely available for everyone who needs them.

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Appendix B. Online informed consent

Estimado/a participante:

Muchas gracias por interesarte en nuestro estudio.

A continuación vamos a realizarte una serie de preguntas que se orientan a saber si cumples con los criterios de admisión y de exclusión del estudio.

Necesitarás aproximadamente 20 minutos para responder a todas las preguntas.

En el caso de que no cumplas alguno de los criterios te informaremos en ese mismo momento.

Si completas estos cuestionarios nos pondremos personalmente en contacto contigo para confirmar que puedes entrar.

Antes de contestar los cuestionarios es **fundamental que leas la información siguiente**:

Es muy importante que entiendas que para poder participar en el estudio hay unos **criterios que debes cumplir**:

- Los criterios de inclusión son los siguientes:
- Tener al menos 18 años.
- Tener acceso a Internet y un correo electrónico.
- Cumplir los criterios diagnósticos de un trastorno emocional (DSM-V). Por trastorno emocional nos referimos a los siguientes: Depresión, Ansiedad Social, Ansiedad Generalizada, Trastorno de pánico, Agorafobia, Trastorno obsesivo compulsivo.

Los criterios de exclusión son los siguientes:

- Padecer esquizofrenia.
- Trastorno bipolar.
- Dependencia y/o abuso de sustancias y/o alcohol.
- Enfermedad médica de consideración que impida la realización del tratamiento psicológico.
- Que haya riesgo de suicidio.
- Recibir otro tratamiento psicológico mientras dure el estudio.
- En el caso de estar recibiendo tratamiento farmacológico, el incremento de dosis o cambio del tipo de medicación.

Nota: Realizar los cuestionarios no garantiza recibir tratamiento. No nos comprometemos a proporcionar tratamiento a aquellas personas que no cumplan con los criterios de participación de este estudio.

Lee con atención lo que viene a continuación, es la **explicación del estudio**:

Tu participación en este estudio implica el acceso al programa de tratamiento psicológico online para los trastornos emocionales, que incluye una serie de técnicas que han demostrado ser eficaces para estos problemas. El objetivo de este programa es el aprendizaje de estrategias de regulación emocional adaptativas que permitan afrontar experiencias o situaciones adversas o estresantes. Sabemos que la manera de afrontar estas situaciones está fuertemente asociada al posterior desarrollo de problemas emocionales.

Este programa consta de 12-16 módulos y en cada uno de ellos aprenderás diferentes técnicas que te ayudarán a conseguir nuevas habilidades para disminuir tu malestar y adaptarte de manera más flexible a las situaciones complicadas que aparezcan en tu día a día.

Este programa lo podrás realizar desde tu casa, de forma totalmente autoaplicada a través de Internet.

En el estudio hay tres grupos.

1. El primer grupo accede de manera inmediata a 12 módulos del protocolo de tratamiento a través de una plataforma virtual denominada Psicología y Tecnología.
2. El segundo grupo recibe los mismos módulos de tratamiento añadiendo algunos componentes terapéuticos más, siendo un total de 16 módulos.
3. Finalmente, el último grupo tiene igualmente acceso al protocolo de tratamiento pero de una manera demorada tras 18 semanas.

La asignación a cada uno de los grupos será aleatoria. Te informaremos por teléfono a qué grupo perteneces.

Antes de continuar lee también esta información, es el **consentimiento informado** que aceptarás si continúas adelante:

Entiendo la naturaleza y el propósito de los procedimientos que entrañan el presente estudio que se me han comunicado previamente.

Entiendo que la investigación está diseñada para promover el conocimiento científico y que la Universitat Jaume I de Castellón usará los datos que yo le proporcione sólo y exclusivamente para esta investigación.

Entiendo que los datos que proporcione serán considerados como confidenciales. Mi nombre o cualquier otra información no se harán públicos en ninguna presentación o publicación de la investigación. El procesamiento y uso de mis datos anónimos se llevará a cabo y se almacenará en papel y en formato electrónico durante 15 años.

Entiendo que puedo retirarme del estudio en cualquier momento, sin dar ningún tipo de explicación y sin ningún tipo de inconveniente para mí.

Entiendo que la Universitat Jaume I de Castellón puede usar los datos recogidos en este proyecto para un proyecto de investigación posterior pero que las condiciones bajo las cuales he proporcionado la información seguirán siendo las mismas.

1. ¿Has leído y comprendido el texto con la explicación sobre criterios de inclusión/exclusión, características del estudio y consentimiento informado?

SÍ

NO

2. Doy mi conformidad para participar en este estudio y soy consciente de que los datos derivados del mismo podrán ser usados para fines de investigación, salvaguardando siempre mi derecho a la confidencialidad y al anonimato.

SÍ

NO

